

Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/US04/042377

International filing date: 17 December 2004 (17.12.2004)

Document type: Certified copy of priority document

Document details: Country/Office: US
Number: 60/530,151
Filing date: 17 December 2003 (17.12.2003)

Date of receipt at the International Bureau: 26 January 2005 (26.01.2005)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)



World Intellectual Property Organization (WIPO) - Geneva, Switzerland
Organisation Mondiale de la Propriété Intellectuelle (OMPI) - Genève, Suisse



THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

January 13, 2005

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE.

APPLICATION NUMBER: 60/530,151

FILING DATE: *December 17, 2003*

RELATED PCT APPLICATION NUMBER: *PCT/US04/42377*



Certified By

Jon W Dudas

Under Secretary
of Commerce for Intellectual Property
and Acting Director of the
United States Patent and Trademark Office

Please type a plus sign (+) inside this box

+

PTO/SB/16 (8-00)

Approved for use through 10/31/2002. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No. EV 325075609 US

INVENTOR(S)

Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
Christopher James	Pearce Neumiller	

☒ Additional inventors are being named on the 1 separately numbered sheets attached hereto

TITLE OF THE INVENTION (500 characters max)

DEFIBRILLATOR/MONITOR SYSTEM HAVING A POD WITH LEADS CAPABLE OF WIRELESSLY COMMUNICATING

Direct all correspondence to:

CORRESPONDENCE ADDRESS

☒ Customer Number

022859

Place Customer Number
Bar Code Label here

OR

Type Customer Number here

<input checked="" type="checkbox"/> Firm or Individual Name	Charles D. Segelbaum Fredrikson & Byron, P.A.				
Address	4000 Pillsbury Center				
Address	200 South Sixth Street				
City	Minneapolis	State	MN	ZIP	55402-1425
Country	USA	Telephone	612-492-7115	Fax	612-492-7077

ENCLOSED APPLICATION PARTS (check all that apply)

<input checked="" type="checkbox"/> Specification Number of Pages	57	<input type="checkbox"/> CD(s), Number	
<input checked="" type="checkbox"/> Drawing(s) Number of Sheets	63	<input checked="" type="checkbox"/> Other (specify)	return post card
<input type="checkbox"/> Application Data Sheet. See 37 CFR 1.76			

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT (check one)

☐ Applicant claims small entity status. See 37 CFR 1.27.

FILING FEE

AMOUNT (\$)160.00

☒ A check or money order is enclosed to cover the filing fees.

☒ The Commissioner is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number:

061910

☐ Payment by credit card. Form PTO-2038 is attached.

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☒ No.

☐ Yes, the name of the U.S. Government agency and the Government contract number are: _____

Respectfully submitted

SIGNATURE

TYPED OR

PRINTED NAME Charles D. Segelbaum

TELEPHONE 612-492-7115

Date

12/17/2003

REGISTRATION NO.

42,138

(if appropriate)

Docket Number: 539.6006.0

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is used by the public to file (and by the PTO to process) a provisional application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the complete provisional application to the PTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop Provisional Patent Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PROVISIONAL APPLICATION COVER SHEET
ADDITIONAL PAGE

PTO/SB/16 (8-00)

Approved for use through 10/31/2002. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Docket Number		539.6006.0	Type a plus sign (+) inside this box	+
INVENTOR(S)/APPLICANT(S)				
Given Name (first and middle [if any])	Family or Surname	Residence (City and either State or Foreign Country)		
Rich	Cardin			
John C.	Daynes			
Doug	Hill			
Eric T.	Hoierman			
Gregory T.	Kavounas			
Irma	Lam			
Judy	Marquardt			
Thomas J.	McGrath			
Michael	McMahon			
Randy	Merry			
Rodney	Merry			
Maren	Nelson			
Rockland	Nordness			
Dana J.	Olson			
James M.	Owen			
Ken	Peterson			
Robert	White			
Peter	Wung			
Craig				

Number 1 of 1

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

#2906661\1

CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10)Applicant(s): **Pearce, et al**

Docket No.

539.6006.0

Serial No.

New

Filing Date

December 17, 2003

Examiner

Not Assigned

Group Art Unit

Not Assigned

Invention: **DEFIBRILLATOR/MONITOR SYSTEM HAVING A POD WITH LEADS CAPABLE OF WIRELESSLY COMMUNICATING**

I hereby certify that the following correspondence:

Provisional Application for Patent Cover Sheet, Provisional Patent Application, 63 sheets of informal drawings, return post card, and check in the amount of \$160 to cover the application filing fee.

(Identify type of correspondence)

is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

December 17 2003
(Date)

Joan E. Eckerly*(Typed or Printed Name of Person Mailing Correspondence)*

Joan E. Eckerly
(Signature of Person Mailing Correspondence)

EV 325075609 US*("Express Mail" Mailing Label Number)*

DEFIBRILLATOR/MONITOR SYSTEM HAVING A POD WITH LEADS CAPABLE OF WIRELESSLY COMMUNICATING

TECHNICAL FIELD

[0001] The invention relates to medical devices, and in particular, to defibrillation/monitor systems having a detachable pod with leads.

BACKGROUND

[0002] Each day thousands of Americans are victims of cardiac emergencies. Cardiac emergencies typically strike without warning, oftentimes striking people with no history of heart disease. The most common cardiac emergency is sudden cardiac arrest ("SCA"). It is estimated more than 1000 people per day are victims of SCA in the United States alone.

[0003] SCA occurs when the heart stops pumping blood. Usually SCA is due to abnormal electrical activity in the heart, resulting in an abnormal rhythm (arrhythmia). One such abnormal rhythm, ventricular fibrillation (VF), is caused by abnormal and very fast electrical activity in the heart. During VF the heart cannot pump blood effectively. Because blood may no longer be pumping effectively during VF, the chances of surviving decreases with time after the onset of the emergency. Brain damage can occur after the brain is deprived of oxygen for four to six minutes.

[0004] Applying an electric shock to the patient's heart through the use of a defibrillator treats VF. The shock clears the heart of the abnormal electrical activity (in a process called "defibrillation") by depolarizing a critical mass of myocardial cells to allow spontaneous organized myocardial depolarization to resume.

[0005] Cardiac arrest is a life-threatening medical condition that may be treated with external defibrillation. External defibrillation includes applying electrodes to the patient's chest and delivering an electric shock to the patient to depolarize the patient's heart and restore normal sinus rhythm. The chance a patient's heart can be successfully defibrillated increases significantly if a defibrillation pulse is applied quickly.

[0006] In a scenario where a paramedic is responding to an emergency call with a non-specific patient condition, for example, there has been a car accident. The paramedic will typically carry his or her own defibrillator/monitor, a gurney, and drug box, and other

supplies considered essential. If, perhaps, the car has driven off an embankment, the paramedic will have a long distance to run with all this equipment. This slows the response time to a call where someone may be bleeding to death. Smaller lighter equipment is always demanded by paramedics to save them time and effort, and allow them to get to the scene earlier. For just this reason, some paramedics will opt to carry only an AED (Automatic External Defibrillator) to the scene, and move the patient into the ambulance as quickly as possible, where other, more advanced monitoring equipment is available. In some countries, this approach has been incorporated into standard operating protocols, where the ambulance carries both ALS (advanced life support) equipment (which typically would include a multi-parameter monitor and defibrillator) and an AED. This approach, while effectively giving the user the choice of equipment to carry, forces the paramedic to learn two different defibrillators. The approach also forces the paramedics to possibly transfer the patient from one machine to the other once in the ambulance. It also adds costs to the ambulance service and potentially causes lost data between the two defibrillators for critical minutes, which may negatively impact the ability of EP Lab (Electro-Physiology Lab) doctors to determine the original cardiac condition.

[0007] Previous attempts to address the issue of product weight have done so by creating a manual defibrillator that separates from a patient monitor, or an AED, which separates from a single-channel patient monitor, or a manual defibrillator/pacemaker that separates from a 12-lead ECG monitor. These products suffer from limitations by the present standards, such as: limited capture of patient data, limited ability to monitor all necessary patient vital signs, and possible unreliability due to the nature of the electrical contacts between the two devices (e.g., dirt, mud, and damage to the case which could affect alignment of electrical contacts, thus preventing full functionality of the devices when mated).

[0008] In a scenario where a patient on a gurney is being transported through narrow doorways and down stairwells to an ambulance, or the situation where a patient is in an ambulance moving on a road at high speed with patient cables and IV (intravenous) lines running between the patient and other equipment within the ambulance. If the monitoring/therapeutic device is large or the route to the ambulance is particularly difficult, the paramedic might elect to carry the device separately from the gurney to prevent the device falling off the gurney or onto the patient. However, the paramedic is now restricted in

his or her ability to detach the device from the gurney due to the number and length of patient cables between the device and the patient. Similar restrictions occur once the patient is loaded into a patient transport vehicle or when the patient is transferred from the ambulance to the emergency department. The number of cables and their similarity in color or dissimilarity in length can all contribute to delays in treating or transferring the patient and can restrict the paramedics mobility when treating the patient in a confined space. Additionally, delays may be created with cables having become tangled, or even cut, from their previous uses.

[0009] The prior art has tried to solve this problem by providing a wireless module that transmits data to a patient monitor, such as the MobiMed offered for Sale by Ortivus. However, this device does not include a defibrillator and does not have the capability to provide any therapeutic functions such as pacing, defibrillation or synchronous cardioversion without attaching another monitor/defibrillator to the patient, which further increases the complexity and ambulance provider cost. Additionally, the Ortivus patient module does not offer replaceable batteries so functionality is severely limited if a reliable source of battery charging is not available, or if the transport time is excessively long. Additionally, the Ortivus device does not offer a display to allow visual monitoring of the waveforms or vital signs if the other module is out of range or obscured.

[0010] Another problem arises when hospital personnel want to charge the batteries of the defibrillator/monitor, but don't want to have to place the unit in a docking station in order to charge the batteries. There also arises the issue of patient confidentiality, such as recently raised by the Federal HIPAA (Health Insurance Portability and Accountability Act) regulations, when identical looking patient monitors are accidentally swapped by users.

[0011] Another problem may occur in a situation where two or more sets of paired wireless devices are used in the same general area. This type of problem could occur in a number of different (medical or non-medical) applications. For example, medical device A is comprised of two parts, a patient data acquisition module (AA) and a display module (AD). The two parts communicate with each other via one of many wireless methods. Medical device B is comprised of two similar parts patient data acquisition module (BA) and display module (BD). In the event of a mass casualty incident, where medical personnel are attending to more than one patient, two or more patients may be laying close to each other.

Suppose patient X is being attended to by the user of device A, and a different user who is using device B is attending to patient Y. Patient X's vital signs are being acquired by acquisition module AA and transmitted to display module AD. Patient Y's vital signs are being acquired by acquisition module BA and transmitted to display module BD. A problem would arise when, in the state of confusion typically existing in a mass casualty incident, the two display modules become switched. In this case, the user of display module AD would be viewing the vital signs transmitted from Patient X while attending to Patient Y. This could result in inappropriate administration of drugs or other therapy with potentially serious consequences. The acquisition modules would still be paired to the appropriate display modules, and would still be functioning properly, but the user would be viewing the wrong patient's vital signs.

[0012] Other problems with wireless communications include the fact wireless communications methods cannot be visually assessed by the user prior to failure, such as a broken or damaged cable can. Wireless communications may not be permitted in critical areas, such as an aircraft environment, in military use, or elsewhere. Some wireless communications means have delays between sending a message and getting a response which are too long for therapeutic and other needs. There is a risk of the user not being able to find a cable when, for instance, a critical therapy has to be administered where the wireless link cannot support it.

SUMMARY

[0013] The invention overcomes the problems of the prior art. The invention provides an external defibrillator comprising a patient monitor and a defibrillator/monitor. The patient monitor is referenced as the pod herein and is generally used for monitoring parameter data for a patient having a cardiac episode. The defibrillator/monitor is referenced as the base herein and is generally used for collecting and displaying the data received from the pod as well as for treating the patient following diagnosis of the data. As such, the pod and base are configured to support communication therebetween. The communication between the pod and base may be provided via direct electrical connection or may be provided wirelessly. Generally, the base is intended to releasably hold the pod. In one embodiment, the base accommodates the pod within a slot defined by the base. The base may be configured to

accommodate pods of a variety of different sizes, with one or more of the pods being universally secured to the base using a common latching assembly. The latching assembly may comprise one or more guide rails adapted for controlling motion of the pod in both vertical and horizontal directions when the base accommodates the pod. Also included in the assembly is a latch for securing the pod to the base. The latch is operatively coupled to the base and aligns with a matching cavity defined by the pod. The base is adapted for direct electrical connection to one or more of the pods. The guide rails of the latching assembly are adapted for aligning the base and the pod to facilitate such electrical connection. When having a direct electrical connection therebetween, the base and the pod are interconnected via a base-to-pod connector. If the base accommodates more than one pod, the pods can each be connected to the base via their own base-to-pod connector. Alternatively, when more than one pod is accommodated by the base, one pod may have a base-to-pod connection, while the other pods have pod-to-pod connections in which an electrical connection is formed between the pod electrically connected to the base and the other pods.

[0014] In certain embodiments, cable, tethered to and housed within the base, is used to provide the direct electrical connection between the base-to-pod connector and the base. A first end of the cable is coupled to the connector located within a connector cavity of the base, while a second, or opposite, end of the cable is connected to the base. The first end of the tethered cable, with the connector, is configured for removal from the cavity to provide a direct electrical connection between the base and pod when the base does not accommodate the pod. When the base and pod have a direct electrical connection therebetween, the base is configured for automatically detecting the wired connection so as to establish immediate communication between the base and the pod.

[0015] The slot used to accommodate the one or more pods can be further used to house one or more modules. As such, power can be provided to such modules housed in the slot via the base-to-pod connector on the base. Alternatively, if the one or more modules housed in the slot is a power supply module, power can be provided from the power supply module to the base via the base-to-pod connector. The base is configured having multiple power supply options. In certain embodiments, the base accommodates a power supply module within the slot and the pod is operatively coupled to the base outside of the slot. In certain embodiments, batteries normally accommodated by the base are substituted with a power

supply module. In certain embodiments, a removable bottom portion of the base comprises a power supply module, thereby enabling the base to accommodate batteries, one or more pods, and the power supply module. The base can be secured in one of many ways to a docking station configured for limiting the base's motion and providing power to recharge the base's batteries as well as to operate the base. The docking station comprises a restraining plate configured for securing the base thereto. The restraining plate is hinged to a backing plate configured for being secured to a mounting surface. In certain embodiments, securement of the base to the restraining plate is facilitated through the insertion of a propeller extending vertically from the restraining plate into a recess defined in the base's lower surface. The plate includes a lever, which when adjusted accordingly, rotates the propeller inside the recess, thereby securing the base to the plate and enabling electrical connection between the base and the docking station. There are other known mechanisms for securing the base to the docking station which can be used. The docking station can be used for other purposes, some of which include connecting the base to a network, docking a pod, recharging of the pod's batteries, pairing of the base to a pod, and storage of the base and pod. The pod's batteries can also be wirelessly charged by using the base in a variety of ways. A primary coil connected to line voltage and located within the base can generate line voltage within a secondary coil located with the pod and operatively coupled to the battery. Alternatively, a first capacitive plate connected to line voltage and located within the base can generate line voltage on a second plate located with the pod and operatively coupled to the battery.

[0016] The pod generally comprises one or more batteries, a plurality of lead inputs, and a transceiver used for wirelessly communicating with the base. The lead inputs are used for collecting ECG information or for monitoring patient parameters including blood pressure, pulse oximetry, capnography, temperature, and CO₂ concentration. In certain embodiments, the pod includes a display adapted for presenting information being transmitted to the base. The power for the pod is generally routed from the batteries through a power module to a main power and data bus. From the bus, the power is distributed to a system controller module used for controlling interaction between all of the pod's modules and interaction with the base, a patient parameter module used for monitoring all data from the inputs, and a user interface module primarily used for allowing the user to interact with the pod. The base

comprises one or more batteries, a display, a transceiver used for wirelessly communicating with the pod, and modules for synchronizing, processing, and interpreting patient parameter data acquired from the pod. The power for the base is generally routed from the batteries through a power module to a main power and data bus. From the bus, the power is distributed to an interconnect module used for detecting how the pod is connected to the base, a therapy module used for synchronizing shocks based on the patient data acquired from the pod, a system controller module used for controlling interaction between all of the base's modules and interaction with the pod, and an user interface module primarily used for allowing the user to interact with the base. It is contemplated that the pods and bases are scalable in terms of functional capability. The base is configured for one or more of the following: automatically detecting size and capabilities of one or more pods paired with the base, automatically detecting power supplies linked to the base and selecting the best power supply source for the base's functions, automatically pairing one or more pods to the base upon initial power up of the base, periodically verifying proper base and pod pairing, centrally monitoring one or more pods from the base, periodically locating one or more pods lost or forgotten after having been removed from the base, centrally processing patient parameter data from one or more pods in order to select and display data from one of the pods, and centrally monitoring connection quality between one or more pods and the base. The pod may be configured for automatically detecting power supplies linked to the pod and selecting the best power supply source for the pod's functions.

[0017] The base is configured to accommodate the pod; however, the pod may be removed and used remotely from the base. When the base accommodates the pod, the base and pod generally communicate via electrical connection using electrical leads or contacts. Such an electrical connection is generally used for recharging the pod's batteries. When the pod is removed from the base, the base and pod generally communicate wirelessly using a wireless link. The pod includes a display for presenting patient information needed by medical personnel at the emergency site. The display generally includes a screen or monitor for displaying various patient parameters including ECG waveforms and blood pressure readings, one or more controls for initiating patient parameter testing, one or more warning signals for indicating pod failures such as communication breakdown between the pod and the base, and a plurality of status lights for indicating pod parameters such as battery voltage

and connection quality. In protecting the connection points of the patient cables to the pod, the pod includes a carrying handle formed so that it extends above the connection points of the cables and as such, protects the cables from impact or incidental disconnection. The pod is configured for use with a lead separator that defines a plurality of holes therein. Each hole of the lead separator is used for securing, separating, and organizing a lead of the pod. The pod is adapted for use with a pod carrying bag. The bag contains a plurality of compartments, with at least one compartment configured to receive a pod and at least one compartment configured to receive one or more pod components. The bag has one or more cutout portions therein which enable the pod to be accommodated and electrically connected to the base while being contained within the bag. The bag is comprised of a flexible, yet sturdy material. There are a variety of ways by which the bag can be carried, some of which involve the use of shoulder straps or handgrips. The pod is configured for securement to a patient gurney in a variety of different positions that enable easy access and visibility of the pod by medical personnel and limited pod movement relative to the patient. In certain embodiments, the pod is operatively coupled to the patient gurney through the use of brackets. In certain embodiments, the pod is operatively coupled to the patient through the use of attachable pod side flaps. In certain embodiments, the pod is operatively coupled to the patient gurney through the use of a shoulder strap attached to the pod or to a bag containing the pod. In certain embodiments, the pod is operatively coupled to the patient gurney through the use of a holding tray that is operatively coupled to the gurney and sized to receive the pod or pod and pod carrying bag.

[0018] Modules other than the pod exist which are removably accommodated by the base. When the base accommodates such removable modules, the base and the modules generally communicate via electrical connection using electrical leads or contacts. When one or more of the removable modules are removed from the base, the base and removed modules generally communicate through electrical cables or wirelessly using a wireless link. In certain embodiments, the removed modules communicate wirelessly with the pod using a wireless link. The base generally includes a display for presenting the transmitted patient parameter data and a control panel including one or more interfaces for selecting parameters involving operation, exhibiting patient parameter data, and pacing. The base accommodates removable modules generally including the pod, defibrillator paddles, a power supply, a

battery charger, a keyboard, a printer, a mechanism for cellular communication, and a processing unit. The base is configured to automatically monitor the removal, usage, and condition of the modules via logging of the removal and return events involving the modules. In certain embodiments, one of the removable modules of the base comprises an AED used for administering shock therapy following patient diagnosis. The pod is used for monitoring patient parameter data and transmitting the data to the base. In certain embodiments, the pod is adapted to store such patient parameter data. In certain embodiments, the pod includes an AED so the pod can be used to administer shock therapy to the patient following instruction from the base. In certain embodiments, the pod is configured to transmit the patient parameter data via the electrode sensors attached to the terminal lead points of the pod, which are located at the patient. The pod is adapted to automatically transmit the monitored patient parameter data in real time to the base in a wireless manner. As such, the data is transmitted in a continuous stream. The pod and base are each configured to automatically wirelessly transmit patient parameter data in real time in a wireless manner to one or more modules independent of the base. One such module independent of the base is an Electric Patient Care Report (ePCR) device used for storing and analyzing the data for diagnostic and treatment purposes. Consequently, the ePCR, as well as the base, are adapted for fully displaying an episode of a cardiac related incident without prior data dumping to the base or ePCR. In certain embodiments, the ePCR provides one or more functions generally provided by the base. In certain embodiments, the ePCR is a module to the base. The base is adapted for automatically wirelessly transmitting patient parameter data to a treatment module for timely coordinating electric therapy with other types of therapy, such as chest compressions, for the patient. The base is configured to wirelessly communicate with an implanted defibrillator to provide further processing and diagnosis regarding data collected by the defibrillator. The pod and base are each configured for automatically wirelessly transmitting patient parameter data to a remote access point. Such remote access points are generally located remote from the pod and base and, similar to the ePCR, are adapted for analyzation of the transmitted data for diagnosis and treatment purposes. The wireless communication used with the base can be adapted to other applications. In certain embodiments, messages are wirelessly transmitted away from the base to provide status checks regarding components, such as batteries, of the base and the modules that the base accommodates.

These status checks may be in the form of timed self-tests, whereby technicians or customers are subsequently notified of the condition of the components of the base and modules. In certain embodiments, messages are wirelessly transmitted to the base to provide software upgrades for the base. The wireless communication used between the base and pod can be adapted to other applications. In certain embodiments, in-service training by medical personnel is conducted with a trainer using a pod that is wirelessly transmitting patient parameter data to a plurality of bases each used by a trainee. In applications where medical personnel bring both the base and pod to the emergency site, the wireless aspects of the invention are utilized through display medium for the personnel, such as glasses or headset. Such medium provides wireless communication with the base and enables the personnel to view patient parameter data transmitted from the base more conveniently.

[0019] The external defibrillator is provided having a tiered alarm reporting scheme for delineating between critical faults, non-critical faults, and other routine diagnostic reminders or test reports within the defibrillator. In certain embodiments, the configuration of the reporting scheme is based on the functioning configuration of the pod and base of the defibrillator. In certain embodiments, various levels of user help are pre-configured for the reporting scheme. As such, following an alarm event, the particular level of user help that is used is dependent on the experience level of the user. In certain embodiments, the defibrillator is configured to not display waveforms representing patient parameter data. The defibrillator is configured for operatively coupling one or more of the following thereon: an accessory container, a securing bracket for defibrillation paddle, an adjustable carry handle, a gurney hook, and a display guard. The accessory container generally includes a strap for operatively coupling to an upper portion of the defibrillator and a lower retaining pocket for operatively coupling to a lower portion of the defibrillator. The securing bracket for defibrillator paddle includes a raised portion bordering at least a portion of the perimeter of the paddle in order to protect the paddle, and a latch thereof the raised portion which securely fastens the paddle within the bracket. The adjustable carry handle is secured to the defibrillator via a set screw and is adapted for rotation about the set screw so as to be set in line with the center of gravity of the defibrillator. In certain embodiments, the gurney hook is formed of a strong wire like material and is configured for attachment to adjustable handle enabling rotation about its point of attachment from a neutral position to a position where it

can engage a gurney rail. In certain embodiments, defibrillator is designed with a recessed portion for accommodating the display guard. As such, the guard appears to be an integral part of the defibrillator casing.

[0020] The base and pod each have separate but interchangeable removable/rechargeable batteries. Generally, upon powering, both the base and pod are powered by their respective batteries. However, if the pod is electrically connected to the base and the base is connected to an external power source, the pod is adapted to stop using its own battery and the base is adapted to start supplying external power to the pod through a power bus located therebetween. If the base is not connected to external power source, then the pod is configured for using the energy of its own battery until it reaches a "low power" state, upon which, the pod is configured for requesting a power transfer from the base through the electrical connection. Following the pod's request, the base is adapted for transferring power to the pod unless the base has reached a "low power" state, upon which, the base is adapted for initiating an alarm informing the user that the base should be connected to external power source or the base and pod batteries should be replaced. A battery-charging maintenance scheme is provided for the base and pod. When the base and pod are electrically connected, a microprocessor located within the base is adapted for interrogating the base and pod batteries via a multiplexer located within the base. The pod battery is interrogated via a communication bus between the base and pod. The battery information supplied to the microprocessor includes voltage and current parameters, battery's charge level, and a battery serial number. If the microprocessor determines charging is necessary, a power module located within the base and connected to an external power source is configured for charging the batteries. The power module is isolated from the rest of the base circuitry so it can charge the batteries even when base is turned off, thereby reducing the amount of circuitry needing power during the charging process. The pod battery is charged via a battery charger bus between the base and the pod. Once batteries for the pod and base are fully charged, the power module is configured for using incoming power from the external power source to power the base and pod via the power bus. When the base and pod are not electrically connected, a power processor located within the pod is configured for receiving pod battery information through the communication bus, and routing this information to signal processor located within the pod. The signal processor is adapted for processing the battery

information and transmitting the information to the base. In certain embodiments, information regarding the charge on the batteries is monitored and indicated on the display of the defibrillator. In certain embodiments, battery-charging circuitry for the base is provided with an external adapter configured for coupling to the base. An activation/deactivation scheme is provided for the base and pod, whereby one of the base and pod, following power up or shut down, is configured to send a signal to provide the same for the respective other. In certain embodiments, this signal would result from the user pressing an on/off button. The scheme can be used for both electrical and wireless connection of the base and pod.

BRIEF DESCRIPTION OF DRAWINGS

[0021] FIG. 1A is a pictorial representation of an external defibrillator having a patient module with a defibrillator/monitor in an embodiment of the present invention;

[0022] FIG. 2A is a pictorial representation of a latching assembly on a defibrillator/monitor in an embodiment of the present invention;

[0023] FIG. 3A is a pictorial representation of a mating assembly on a defibrillator/monitor in an embodiment of the present invention;

[0024] FIG. 4A is a pictorial representation of a mating assembly having a tethered connector in an embodiment of the present invention;

[0025] FIG. 4A' is a pictorial representation of a tethered connector as shown in FIG. 4A;

[0026] FIG. 5A is a pictorial representation of an alternate use for a patient module docking station within a defibrillator/monitor in an embodiment of the present invention;

[0027] FIG. 5A' is a front profile view of a defibrillator/monitor providing an alternate power supply option in accordance with an embodiment of the present invention;

[0028] FIG. 5A'' is a front profile view of a defibrillator/monitor providing an alternate power supply option in accordance with an embodiment of the present invention;

[0029] FIG. 5A''' is a front profile view of a defibrillator/monitor providing an alternate power supply option in accordance with an embodiment of the present invention;

[0030] FIG. 6A is a pictorial representation of storage assembly for a defibrillator/monitor in an embodiment of the present invention;

[0031] FIG. 6A' is a pictorial representation of storage assembly for a defibrillator/monitor in an embodiment of the present invention;

[0032] FIG. 7A is a pictorial representation of a multiple patient module storage and attachment assembly in an embodiment of the present invention;

[0033] FIG. 8A is a pictorial representation of a docking station for a defibrillator/monitor in an embodiment of the present invention;

[0034] FIG. 8A' is a pictorial representation of a docking station and defibrillator/monitor as shown in FIG. 8A;

[0035] FIG. 8A'' is a side profile view of a docking station as shown in FIG. 8A;

[0036] FIG. 8A''' is a top profile view of a docking station as shown in FIG. 8A;

[0037] FIG. 9A is a side rear profile view of a docking station for a defibrillator/monitor in an embodiment of the present invention;

[0038] FIG. 10A is a front pictorial of a docking station for a defibrillator/monitor and patient module in an embodiment of the present invention;

[0039] FIG. 11A is a front profile view of a docking station for a defibrillator/monitor in an embodiment of the present invention;

[0040] FIG. 12A is a pictorial representation of a docking station for a defibrillator/monitor in an embodiment of the present invention;

[0041] FIG. 13A is a front profile view of a docking station for a defibrillator/monitor in an embodiment of the present invention;

[0042] FIG. 14A is a side profile schematic of a defibrillator/monitor and a patient module according to a patient module wireless battery charging embodiment of the present invention;

[0043] FIG. 15A is a side profile schematic of a defibrillator/monitor and a patient module according to a patient module wireless battery charging embodiment of the present invention;

[0044] FIG. 1B is an upper level pictorial representation of a patient module in an embodiment of the present invention;

[0045] FIG. 2B is an upper level pictorial representation of a defibrillator/monitor in an embodiment of the present invention;

[0046] FIG. 3B is a schematic view of a patient module in an embodiment of the present invention;

[0047] FIG. 4B is a schematic view of a defibrillator/monitor in an embodiment of the present invention;

[0048] FIG. 5B is a block level diagram of a patient module and a defibrillator/monitor interaction in an embodiment of the present invention;

[0049] FIG. 6B is a block level diagram of a pairing system for a patient module and a defibrillator/monitor in an embodiment of the present invention;

[0050] FIG. 1C is a perspective view of a pod and pod display according to one embodiment of the invention;

[0051] FIG. 2C is a perspective view of a pod and pod display according to one embodiment of the invention, showing batteries positioned within;

[0052] FIG. 3C is a side view of a pod according to one embodiment of the invention, showing the position of the connectors and handle;

[0053] FIG. 4C is a perspective view of a lead separator according to one embodiment of the invention;

[0054] FIG. 5C is a perspective view of a pod carrying bag according to one embodiment of the invention;

[0055] FIG. 6C is a side view of the pod carrying bag displayed in Figure 5 in a connected position with a defibrillator;

[0056] FIG. 7C is a front view of a pod carrying bag having a shoulder strap in accordance with one embodiment of the invention;

[0057] FIG. 8C is a side view of a standard patient gurney;

[0058] FIG. 9C is side view of a patient gurney adjusted to allow for pod mounting;

[0059] FIG. 10C is an elevated view of a pod positioned on top of a patient;

[0060] FIG. 11C is a perspective view of a pod shoulder strap secured to a gurney rail;

[0061] FIG. 12C is a perspective view of a pod holding tray secured to a gurney.

[0062] FIG. 1D is a block pictorial representation of a defibrillator-monitor in accordance with certain embodiments of the invention;

[0063] FIG. 2D is a block diagram demonstrating embodiments of potential wireless communication channels for a base station and pod of the defibrillator-monitor of FIG. 1D;

[0064] FIG. 3D is a block diagram demonstrating further embodiments of potential wireless communication for the pod of the defibrillator-monitor of FIG. 2D;

[0065] FIG. 4D is a block diagram demonstrating further embodiments of potential wireless communication for the base station of the defibrillator-monitor of FIG. 2D;

[0066] FIG. 5D is a flow diagram showing steps for a system that automatically monitors the health status of the defibrillator-monitor of FIG. 1D;

[0067] FIG. 6D is a block diagram demonstrating a set-up for in-service demonstrations and training for emergency personnel in accordance with certain embodiments of the invention.

[0068] FIG. 1E is a perspective view of an accessory container of the invention;

[0069] FIG. 2E is a cross-section view of an accessory container of the invention;

[0070] FIG. 3E is an end view of a defibrillator device configured for mounting an accessory container;

[0071] FIG. 4E is a cross-section of a defibrillator device configured for mounting an accessory container and an accessory container;

[0072] FIG. 5E is a perspective view of a defibrillator device configured for mounting an accessory container;

[0073] FIG. 6E is a cross-section of a defibrillator device configured for mounting an accessory container;

[0074] FIG. 7E is a cross-sectional view of the modified shoulder harness bracket of the invention;

[0075] FIG. 8E is a perspective view of the modified shoulder harness bracket;

[0076] FIG. 9E is a perspective view of a securing bracket for a defibrillator paddle;

[0077] FIG. 10E is an end view of a defibrillator unit with an adjustable handle;

[0078] FIG. 11E is an end view of a defibrillator unit with an adjustable handle;

[0079] FIG. 12E is a perspective view of a gurney hook;

[0080] FIG. 13E is a side view of the adjustable handle with a gurney hook attached;

[0081] FIG. 14E is an end view of a defibrillator equipped with the adjustable handle and gurney hook;

[0082] FIG. 15E is a perspective view of a defibrillator with an integrated display guard;

[0083] FIG. 16E is a cross section of the display guard showing its relation to the display screen;

[0084] FIG. 17E is a cross section of the display guard with a bumper element;

[0085] FIG. 18E is a cross section of the display guard with a bumper element and an access opening;

[0086] FIG. 1F is a pictorial display of a patient module and a defibrillator/monitor in a power sharing embodiment of the present invention;

[0087] FIG. 2F is a schematic view of a defibrillator/monitor providing battery charging control of a patient module in an embodiment of the present invention;

[0088] FIG. 3F is a schematic view of a defibrillator/monitor battery charging scheme in an embodiment of the present invention;

DETAILED DESCRIPTION

[0089] The following detailed description is to be read with reference to the figures, in which like elements in different figures have like reference numerals. The figures, which are not necessarily to scale, depict selected embodiments and are not intended to limit the scope of the invention. Skilled artisans will recognize the examples provided herein have many useful alternatives falling within the scope of the invention.

Mechanical and Electrical interconnections

[0090] With reference to Figure 1A, a pictorial representation of an external defibrillator having a patient module with a defibrillator/monitor in an embodiment of the present invention is shown. External defibrillator 10A is comprised of two components the patient module (pod) 12A and the defibrillator/monitor (base) 14A, which communicate patient data wirelessly and share common replaceable battery technology. Pod 12A generally rests within base 14A, generally in the back of base 14 as will be discussed in more detail below. The user, during an emergency, has the option of carrying base 14A with pod 12A attached or simply carrying pod 12A to the emergency site. Since pod 12A is smaller and lighter than base 14A, generally it will be easier for the user to simply carry pod 12A. By carrying pod 12A, the user is free to carry more ALS equipment and not be slowed by the heavier and more awkward base 14A.

[0091] With reference to Figure 2A, a pictorial representation of a latching assembly on a defibrillator/monitor in an embodiment of the present invention is shown. Latching assembly 16A is used to attach pod 12A to base 15A. Latching assembly 16A is provided with guide ribs 18A & 18A', which provide control motion in both the horizontal and vertical direction, aligning base-to-pod interface connector 20A with a similar connector (not shown) on pod 12A. Latch 22A actuates automatically when pod 12A is placed within slot 17A. When pod

12A is lowered within slot 17A, latch 22A will align with a matching cavity on pod 12A to hold pod 12A within slot 17A. When the user wants to remove pod 12A from slot 17A, they simply press button 24A, which pushes the spring loaded latch 22A back within rear wall 26A of slot 17A. Pod 12A is released and the user simply pulls pod 12A from slot 17A. It is further contemplated pod 12A could be spring released by springs placed at the base of ribs 18A & 18A' or perhaps a spring placed within base-to-pod connector 20A. It is also further contemplated base-to-pod connector could be most any type of connector such as a USB port, an AC power connector, an RS-232 connector or any other type of connector known to those skilled in the art without departing from the spirit of the invention. In addition, it is contemplated pods of different sizes could be used within slot 17A. For example, a large pod would be guided in place with ribs 18A & 18A' and held with latch 22A. If a smaller pod were being used, then the smaller pod would be guided in place with rib 18A so pod 12A aligns with base-to-pod connector 20A and held in place with latch 22A.

[0092] With reference to Figure 3A, a pictorial representation of a mating assembly on a defibrillator/monitor in an embodiment of the present invention is shown. Mating assembly 30A comprises slot 32A which can house two types of pods 33A' and 33A''. Since both pods 33A' and 33A'' have the same dimension in the horizontal, both pods 33A' and 33A'' are capable of fitting within slot 32A. When large pod 33A' is fit within slot 32A it takes up generally all the available room within slot 32A. When small pod 33A'' is placed within slot 32A only the room within upper portion 34A is taken up. Both pod 33A' and 33A'' are held in place by attachment to base-to-pod connector 29A. It is contemplated, however, a latch assembly similar to that of Figure 2A could be utilized to ensure pods 33A' and 33A'' remain within slot 32A without departing from the spirit of the invention.

[0093] With reference to Figure 4A, a pictorial representation of a mating assembly having a tethered connector in an embodiment of the present invention is shown. In this embodiment, a pod similar to 12A rests within slot 40A and connects to base-to-pod connector 42A, which allows base 39A and a pod to communicate with each other. Base-to-pod connector 42A rests freely within connector cavity 44A, which allows connector cable 46A to retractably exit and enter base 39A as shown in Figures 4A and 4A'. Tethered cable 46A allows a pod to mate with and rest within base 39A or mate with base 39A when not docked within slot 40A. It is generally preferred base 39A communicate with a pod through tethered cable 46A.

since communications through a direct connection is generally faster as is discussed in more detail below. This is especially the case in the present embodiment as base 39A is equipped with a USB bus, which provides quick communication of information between a pod and base 39A. Base 39A is also able to automatically detect when tethered cable 46A is plugged in so direct communications can be established immediately. Preferably a direct communication between a pod and base 39A is established whenever possible. This automatic establishment of direct communication between a pod and base 39A includes when a pod is docked within base 39A and a connection is made between a pod and base 39A through connector 42A.

[0094] Generally base 39A and a pod communicate wirelessly to assist in preventing the tangling of cables, which can occur between a patient and base 39A, particularly when transporting patients. Patient cables are typically inspected on a routine basis to check integrity, but this cannot be done when a wireless (i.e. non-physical) link is used. Therefore, tethered cable 46A provides a back-up system for use when the wireless link between pod 12A and base 14A fails for whatever reason. Tethered cable 46A also provides the added advantage in that the user cannot lose cable 46A because it is tethered to base 39A. The back up system also includes a user interface message warning the user when the wireless link is about to be compromised due to detected noise or lack of timely data transmission. Similar to the discussion above, wireless links can impose a delay in communication between a pod and base 39A longer than may be experienced with a cable. When communications between base 39A and a pod require a faster response time (such as application of synchronous cardioversion or pacing where information from a pod must be transmitted to base 39A), the user is advised of the need to plug cable 46A into the pod. The user is provided a user interface message to inform them of the need to attach cable 46A. For example, the user may receive an audio tone from a speaker (not shown) or visual message on patient display 52B (Figure 2B) such as "Warning: poor reception; connect data cable to avoid losing patient data!"

[0095] With reference to Figure 5A, a pictorial representation of an alternate use for a patient module docking station within a defibrillator/monitor in an embodiment of the present invention is shown. As discussed above, typically a pod is placed within a docking station such as latching assembly 16A and mating assembly 30A when the pod is not in use or when

base 51A is carried to an emergency site. As an alternate use of a docking station, the embodiment of Figure 5A allows for an AC power supply 50A to be placed within the docking station and to provide power to base 51A. Power supply 50A would transfer power to base 51A through a base-to-pod connector (not shown) similar to connector 20A. Upon power supply 50A being plugged into a wall outlet via power cord 54A, power LED 52A provides an indication to the user notifying them power supply 50A is powering 51A and/or charging the base's battery. Power supply 50A is typically used when for example; a pod is being used on a patient such as on a gurney or next to the patient to provide constant power and reduce battery depletion. Power supply 50A could also be used when the user desires to substantially power base 39A through line power. Thus an alternate pod mounting device would have to be provided as will be discussed in more detail below.

[0096] With reference to Figures 5A', 5A'', and 5A''', a front profile view of a defibrillator/monitor providing an alternate power supply option in accordance with an embodiment of the present invention is shown. Figures 5A' and 5A'' show a modular and an integrated defibrillator/monitor 14A with multiple power supply options. However, unlike the embodiment of Figure 5A, the present embodiments are able to house pod 12A and provide for an alternate power supply. In Figures 5A' and 5A'', base 53A and 55A typically are powered by dual batteries 56A. In the alternative, bases 53A and 55A could be powered by A/C power module 58A. In these embodiments, batteries 56A are replaced with A/C power module 58A. Module 58A is then connected to A/C power to power base 53A and 55A without having to remove the pod. In another embodiment shown in Figure 5A''', base 49A has a removable bottom section 59A able to accommodate A/C power module 57A. Therefore, base 49A is able to accommodate a pod and an alternate power supply.

[0097] With reference to Figures 6A, and 6A', a pictorial representation of storage assembly for a defibrillator/monitor in an embodiment of the present invention is shown. Figure 6A shows base 61A with brass inserts 60A mounted on the side of base 60A. Brass inserts 60A can be used as clips to attach hand paddles 62A, or side-mounted carrying bags, or a bracket 64A to side mount pod 65A. Bracket 64A allows defibrillator 10A the ability to carry various types of defibrillator support equipment. Further, as stated above, the user has the ability to mount a pod outside of its docking assembly so a power supply 50A can be within the docking assembly and the base can be powered from line power as described above. This

alternate mounting assembly provides the advantages of providing easily accessible connectors for troubleshooting and easier access for connection and disconnection of various leads and connectors.

[0098] With reference to Figure 7A, a pictorial representation of a multiple patient module storage and attachment assembly in an embodiment of the present invention is shown. As discussed more thoroughly below pods can come in different sizes generally representing the capability of the pod. For example, smaller pod 74A' would provide only the basic features for an external defibrillator, while medium pod 74A would provide several additional features. In the present embodiment, pods 74A & 74A' can be docked in mounting slot 72A contemporaneously. In one embodiment, pod 74A could be latched within mounting slot 72A communicating with base 71A through connector 73A. Similarly, pod 74A' can be placed within mounting slot 72A contemporaneously with pod 74A and latched in a communicating relationship with base 71A through connector 73A'. In another embodiment, pods 74A and 74A' could be placed within mounting slot 72A without the need for two base-to-pod connectors 73A. In the embodiment, pod 74A and 74A' latch together and communicate through connectors 70A. Then both pods 74A and 74A' are placed within mounting slot 72A and latched in a communicating relationship with base 71A through connector 73A. This embodiment not only limits the amount of connectors needed on base 71A, but also allows the user to choose the amount of functions the pod can perform. For example, if the user simply needed to perform an ECG, then the user could choose to carry small pod 74A'. However, if the emergency situation required additional functions such as monitoring blood pressure in a non-invasive method or a pulse oximeter, then the user would choose to carry medium pod 74A'. In addition, if the emergency situation required all of the available pod functions, then pod 74A' could latched together with pod 74A to provide a large pod having all necessary functions.

[0099] With reference to Figures 8A, 8A', 8AA'', and 8A''', a pictorial representation of a docking station for a defibrillator/monitor in an embodiment of the present invention is shown. Docking station 80A performs two main roles. It restrains base 85A under semi-violent maneuvers (2-5G's) and provides DC power to charge the batteries (not shown) and operate base 85A. Docking station 80A is comprised of restraining plate 81A held to a wall by backing plate 83A. It is contemplated restraining plate 81A could be attached to any

surface such as a horizontal shelf of a vertical wall without departing from the spirit of the invention. Restraining plate 81A provides a ring 82A housing a self-aligning propeller 84A as best seen in Figure 8A'''. When the user desires to dock base 85A as shown in Figure 8A', it is placed on restraining plate 81A where recess 86A fits over ring 82A and propeller 84A fits within opening 88A in plate 90A. When base 85A is properly placed on restraining plate 81A, the user slides lever 92A from unlock position 94A to locked position 96A. Propeller 84A has a quarter turn twist which pulls base 85A to restraining plate 81A when the user slides lever 92A from unlock position 94A to locked position 96A. As lever 92A moves towards locked position 96A electrical power connection 98A will mate with power connection 100A as base 85A is pulled closer to restraining plate 81A. When connectors 98A and 100A make a good electrical contact, indicator 102A illuminates informing the user a good electrical connection has been made between base 85A and docking station 80A. It is of note that no power is applied to connector 100A until a closed circuit connection is made with connector 98A. Therefore, if base 85A is not docked at docking station 80A, then there is no power applied at connector 100A. It is contemplated when lever 92A is in locked position 96A, a short electrical pulse is sent to connector 100A to verify it is in electrical contact with connector 98A.

[00100] When base 85A is locked to restriction plate 82A docking station 80A provides power to base 85A. When in locked position 96A, docking station 80A restricts the base's up and down, side to side movement to prevent damage to base 85A. It is contemplated docking station 80A could also dock a pod. It is further contemplated docking station 80A could also provide communications from base 85A to a network, such as is described in commonly owned U.S. Patent Application No. 10/378,001 filed February 28, 2003 titled "Medical Device Status Information System", the entire content of which is incorporated herein by reference. Finally, when the user has removed base 85A, restriction plate 81A quickly rotates out of the way for compact storage along axis 104A as more clearly shown in Figure 8A''.

[00101] With reference to Figure 9A, a side rear profile view of a docking station for a defibrillator/monitor in an embodiment of the present invention is shown. Docking station 110A is comprised of sliding plate 112A, rollers 114A, ribs 116A, and latch 118A. In use, base 111A is modified with guides 120A held in place by screw, bolts or the like, which slide

under ribs 116A when base 111A is placed upon and slid on sliding plate 112A. Rollers assist in sliding base 111A along sliding plate 112A. When base 111A is fully within docking station 110A, latch 118A engages a notch on the underside of base 111A, which prevents base 111A from exiting sliding plate 112A. When guides 120A are within ribs 116A, base 111A is unable to move from side to side. Thus latch 118A in combination with guides 120A and ribs 116A prevent any substantial movement of base 111A. Further, when base 111A is fully within docking station 110A, connector 122A mates with another connector (not shown) at the rear of docking station 110A, which provides power to run base 111A and charge the base's battery as well. When the user chooses to remove base 111A from docking station 110A, they would simply press spring loaded button 124A, which releases latch 118A and allows for easy removal of base 111A.

[00102] With reference to Figure 10A, a front pictorial of a docking station for a defibrillator/monitor and patient module in an embodiment of the present invention is shown. In the present embodiment, docking station 130A houses pod 133A and base 131A. It is contemplated docking station 130A could be similar to the structure of docking stations 80A or 110A adjusting of course the size of the docking station to accommodate pod 133A and base 131A. In this embodiment, both pod 133A and base 131A are held securely in docking station 130A and both pod 133A and base 131A are provided with power to charge each respective battery and power each respective device. It is further contemplated pod 133A could be an alternate in the event the pod within base 131A failed. Therefore, in the event of a pod failure, the user would simply return to docking station 130A and retrieve pod 133A place it within the base's docking station (or connect to base 131A through a tethered cord) where base 131A would automatically identify pod 133A and dynamically pair up with pod 133A.

[00103] With reference to Figure 11A, a front profile view of a docking station for a defibrillator/monitor in an embodiment of the present invention is shown. Similar to the docking station of Figure 8A, the present docking station 140A has a locking handle 142A a propeller 144A, and restraining plate 146A. A base would rest on restraining plate 146A, the user would then slid handle 142A into the locking position, thus rotating propeller 144A to hold base 14A to restraining plate 146A. Docking station 140A is held to a wall by screws, bolts, or the like through retaining holes 148A. When the user removes the base by taking

locking handle 142A to the unlock position and lifting the base, restraining plate 146A is moved upward along axis 150A until it rests against back plate 154A. The user then moves locking handle 142A into the locking position, which causes propeller 144A to engage aperture 152A and thus retain restraining plate 146A to back plate 154 thus keeping docking station 130 out of the way for others who may be walking by. A similar embodiment for a docking station capable of stowage after base 14A is removed is shown in Figure 12A.

[00104] With reference to Figure 13A, a front profile view of a docking station for a defibrillator/monitor in an embodiment of the present invention is shown. Docking station 160A is attached to a wall by screw, bolts, or the like through retaining holes 162A. Base 14A is placed upon tray 164A and then the user would turn locking knob 166A to the locking position. By turning locking knob 166A base 14A is pulled back towards the wall until hook 168A engages hook 170A in base 14A. Battery 171A provides power to the base and can recharge the battery if the base carries a rechargeable battery. This allows docking station 160A to be used in an area when line power is inaccessible. When the base is removed from docking station 160A, support 173A is lifted toward wall mount 175A for storage.

[00105] With reference to Figure 14A, a side profile schematic of a defibrillator/monitor and a patient module according to a patient module wireless battery-charging embodiment of the present invention is shown. In the present embodiment, base 181A is able to charge pod battery 188A wirelessly from line power 180A through primary coil 182A located in base 181A and secondary coil 184A located in pod 183A. Bridge rectifier 186A acts to convert A/C line power 180A to a D/C voltage which charges battery 188A of pod 183A. This concept can even be extended to cover a docking station wirelessly charging a base unit as is disclosed in commonly owned U.S. Patent Application titled "Apparatus and Method for Maintaining a Defibrillator Battery Charge and Optionally Communicating" serial number 10/423,805 filed on April 15, 2003.

[00106] With reference to Figure 15A, another side profile schematic of a defibrillator/monitor and a patient module according to a patient module wireless battery charging embodiment of the present invention is shown. In this embodiment, proper alignment of a first plate 192A connected to line power 190A within base 14A and a second plate 194A within pod 193A provides for capacitive coupling. As before, bridge rectifier

196A acts to convert A/C line power 190A to a D/C voltage which charges battery 198A of pod 193A.

Wireless Communication Between the POD and the Defibrillator/Monitor

[00107] With reference to Figure 1B, an upper level pictorial representation of a patient module in an embodiment of the present invention is shown. Generally, pod 12B uses replaceable or rechargeable batteries 16B for power and comprises any combination of the following features: 3, 4, and 5 lead ECG inputs 18B, 12 lead ECG inputs 20B, non-invasive blood pressure (NIBP) input 22B, pulse oximeter input 24B, capnography input (not shown), invasive blood pressure input 26B, temperature input 28B, CO₂ input 30B, additional patient monitoring functions, wireless (RF) transceiver 32B to transmit any or all real time patient data to base 14B. Additionally, pod 12B may include a small display (not shown) replicating some or all of the information such as waveforms, numerical data, and vital signs being transmitted to base 14B. Additionally, pod 12B includes some means by which it can be attached to base 14B for the purpose of carrying base 14B to an emergency scene as is discussed in detail above. Additionally, pod 12B may have a feature allowing it to be easily secured to a gurney or hospital bed, as is discussed in detail below.

[00108] With reference to Figure 2B, an upper level pictorial representation of a defibrillator/monitor in an embodiment of the present invention is shown. Base 14B uses a replaceable or rechargeable battery 50B for power. Batteries 16B and 50B are generally similar in battery chemistry, electrical, and mechanical features to permit the interchangeability between batteries 16B and 50B. Additionally, base 14B comprises a display 52B sufficient to show current and historical patient data, a transceiver (not shown) to send acquired patient data onto a receiving station or third party data receiver (discussed in more detail below), a module 56B to synchronize shocks and pacing pulses to the patient's intrinsic rhythm from data acquired by a pod 12B, an error checking and de-multiplexing module 54B receiving and processing data received from pod 12B, and a data interpretation module 58B which analyzes data acquired by pod 12B and makes certain interpretive statements on the patient's cardiac or respiratory condition, displays vital sign trends, and provides additional functions found in ALS monitoring products.

[00109] With reference to Figure 3B, a schematic view of a patient monitor in an embodiment of the present invention is shown. As discussed above, pod 12B can be powered from a removable/rechargeable battery 60B. Power module 62B processes the incoming power into appropriate power levels for each of the internal components. Power module 62B routes the base's power supply through main power and data bus 64B to system controller module 66B, patient parameter module 68B, and user interface module 70B. As discussed above, pod 12B can be used wirelessly, however, it is preferred if pod 12B is directly connected through a tethered cable 46A or through attachment to a connector 20A to utilize the speed of data bus 64B.

[00110] System controller module 66B controls interaction of all the pod's modules through data bus 64B and interaction with base 14B through wired or wireless (e.g., IrDA, RF, etc.) communication link 72B or through data bus 64B if pod 12B is connected to base 14B. Patient parameter module 68B monitors functions such as invasive blood pressure, patient's temperature, and inputs from the pod leads. Module 68B further collects inputs from EtCO2 module 74B, NIBP module 76B, and SpO2 module 78B through OEM module 80B. Patient parameter module 68B takes all of these inputs and processes them for display and routes only a limited number of inputs to Small LCD display module 82B through user interface module 70B. User Interface module 70B allows the user to primarily interact with pod 12B; however, it is contemplated that user could use the module 70B to interact with base 14B as well.

[00111] With reference to Figure 4B, a schematic view of a defibrillator/monitor in an embodiment of the present invention is shown. Base 14B is powered by a removable/rechargeable battery 84B, which provides power to power module 86B. Alternatively, base 14B could be powered by A/C line power 88B. Power module 86B processes the incoming power into appropriate powered levels for each of the internal components. Power module 86B also routes the pod's power supply through main power and data bus 90B to interconnect module 92B, system controller module 94B, therapy module 96B, and user interface module 98B. Interconnect module 92B is utilized to detect how pod 12B is connected to base 14B (wirelessly, docked, or tethered cable). Similar to system controller module 66B (in Figure 3B), system controller module 94B controls all interaction all of the base's modules through data bus 90B and interaction with pod 12B

through wired or wireless connection communication link 72B or through data bus 90B if pod 12B is connected to base 14B. Therapy module 96B synchronizes shocks and pacing pulses to the patient's intrinsic rhythm from data acquired from pod 12B. Module 96B administers shocks from voltages via the defibrillation cap 100B and, in turn, administers pacing pulses to a patient. User interface module 98B allows the user to primarily interact with base 14B; however, it is contemplated that user could use the module 98B to interact with pod 12B as well. LCD module 102B allows the user to view a patient's monitored parameters. Finally, the user has the option to print out patient information on a printer 104B (e.g., a 100mm strip chart printer).

[00112] With reference to Figure 5B, a block level diagram of a patient module and a defibrillator/monitor interaction in an embodiment of the present invention is shown. In the present embodiment the pods are all scalable, for example; a small pod 110B may provide basic functionality such as ECG acquisition and capability to administer a corrective therapy and the ability to measure SPO₂. A medium sized pod 112B may provide all the basics of small pod 110B and provide additional functionality such as measuring CO₂ and NIBP. And finally, a large pod 114B may provide the user all the functionality of pod 12B. The present embodiment allows for the automatic pairing of base 116B with any pod. Therefore, if a small 110B, medium 112B, or large pod 114B was placed within slot 118B in base 116B, base 116B would automatically detect what size of pod it was being paired with and then match the pod with base 116B. In prior solutions, scalability was limited to the base unit. The present embodiment allows for the scalability to be outside of base 116B and instead with pods 110B, 112B, and 114B. Automatic pairing provides the ability for base 116B to identify the capability of pods 110B, 112B, and 114B without any user input.

[00113] This concept of automatic pairing can also be extended to A/C power supply 120B and D/C power supply 122B, where base 116B could automatically identify what type of power supply is providing power to base 116B and therefore choose the proper circuit to transfer the power to its proper form. It is contemplated this automatic pairing of power supplies 120B & 122B could be extended to pods 110B, 112B, and 114B, which would make pods 110B, 112B, and 114B stand alone devices. If base 116B is able to automatically pair with a power supply and adapt its behavior to the power supply, the docking station 117B need not provide power. Such behavior adaptation would include determining automatically

how fast the battery could charge and just exactly what type of circuitry would be used for charging depending on whether AC power source 120B or DC power source 122B was being used. It is contemplated base 116B could, similar to pods 110B, 112B, and 114B, have a similar scalability in that smaller base stations may have a lower capacity. Furthermore, it is contemplated base 116B could be connected to a personal computer 124B where PC configuration files contain the hardware and software compatibility between the base and the pod. These files would be stored on PC software and when needed would be downloaded to base 116 (discussed in more detail below). Therefore, this would limit the amount of information needed on base 116B with respect to all the possible combinations regarding compatibility between the base stations and the pods.

[00114] With reference to Figure 6B, a block level diagram of a pairing system for a patient module and a defibrillator/monitor in an embodiment of the present invention is shown. The present embodiment facilitates the pairing of pods 132B and 136B with bases 130B & 134B respectively and pre-establishing the authorized combination of the devices. It is preferable the user have minimal or no input with the pairing of the pods with the bases. In prior solutions, designs, e.g., bluetooth designs, required the user to be heavily involved in the pairing of devices. The present invention utilizes a direct connection either via docking of the pod or tethered cord 46A. Therefore, the first time the unit is powered up the devices automatically begin the pairing process. This is often referred to dynamic pairing. For example, once pod 132B was placed within port 131B, base 130B would interrogate pod 132B and initiate the pairing process through authentication and authorization. Dynamic pairing is especially helpful if a pod were to fail and the user desired to put another pod in its place. For example, if pod 132B were to fail, then pod 136B could be docked in slot 131B and base 130B would dynamically pair new pod 136B with base 130B. To verify the pairing was successful, the user can press a button on base 130B or pod 136B, which would initiate an audible confirmation and/or a visual LED on the respective pod or base.

[00115] Proper pod and base pairing is an important aspect in accordance with certain embodiments of the system. With further reference to Figure 6B, an embodiment allows for immediate identification of which patient pod should be displayed when a plurality of pods and main units are in close proximity. This is performed by use of a serial cable (similar to cable 46A), which is normally attached to the back of base 130B, or by momentarily

plugging patient pod 132B into slot 131B of base 130B. Whether by a cable or by docking pod 132B, pod 132B and base 130B identify each other, and communicate only with each other until another such mating of a different pod with base 130B occurs.

[00116] In certain embodiments, the pods are monitored at a central location. A user interface is placed on a display screen and allows the user to select which pod to listen to. The user could test each pod to determine which pod they are trying to connect to. Provided the pod and base are paired, a signal could be injected through the patient as a conduit to verify which pod the base is talking to. As mentioned above, the user could press a button and the pod would blink or enunciate to the user in some manner that it is linked to the base.

[00117] Currently, confusion can occur from multiple bases being confused with each other. In certain embodiments, base 130B could sense the proximity of another base 134B within its range and alert the user of the other base's presence. The user may then be directed to interact with the base or pod, for example, by manually pressing a button thereon. This action would cause the pod or base to respond in some way (e.g. visual or audible alert) to let the user know which is the proper mate to the base or pod. In this way, a user could determine whether or not the devices had accidentally been switched. This would eliminate the possibility of inappropriate diagnosis or delivery of therapy, which might have serious consequences.

[00118] The base could be used as a locator for its paired pod. Although the pod is generally paired to the one base, events may occur in which there are multiple patients, and in turn, multiple bases and corresponding pods. During such events, the multiple pods may be inadvertently transposed, possibly due to identical equipment being used in regard to the multiple bases and pods. In certain embodiments, base 130B and pod 132B provide circuitry to sense the presence of another device within its range (or a specified distance for example five feet) and instruct the user to manually press a button on the module. Pod 132B to which base 130B is paired, would respond, thereby eliminating confusion and possibly avoiding inappropriate diagnosis or delivery of therapy.

[00119] It is contemplated that after having been taken off the base, the pod may be forgotten or lost. In certain embodiments, after a certain amount of wireless inactivity between pod 132B and base 130B, an alarm would go off at base 130B and/or pod 132B. If base 130B is turned off and pod 132B is remotely located, after a certain amount of inactivity, such as

several minutes, pod 132B would enter “sleep mode” (i.e., pod is on, but using a reduced amount of power to maintain its activation) to preserve power. When base 130B was turned back on, RF would be used to detect pod 132B, awaken pod 132B, and initiate an alarm on pod 132B to indicate where pod 132B is located. Alternatively, the user could initiate the pod finder action on the screen at base 130B. This type of locating method is currently used to find wireless phones that have been displaced.

[00120] In certain embodiments, base 130B could act as a hub, which could talk to multiple pods. This would be especially helpful in situations where there was a large response team to several patients. Base 130B would allow the user to select which pod they want to receive patient information from. Base 130B would collect information from the multiple pods but would only display information from one pod. Furthermore, base 130B would be able to make a selection on which pod to show on the screen based upon a patient parameter which indicated the patient was in some sort of immediate danger. This would be performed by routing all data into similar patient analysis algorithms, which would look for abnormalities in the signals.

[00121] It may be important to monitor the wireless connection quality between the base and the pod over their lifetimes. Monitoring this connection would be important because each parameter measured by the pod 132B requires a certain amount of bandwidth to be wirelessly transmitted back to the base 130B. If the signal quality from the pod 132B degrades to a certain level due to connection quality, then a warning would be issued to the user indicating they may need to somehow direct connect the pod 132B to the base 130B either via a cable or dock pod 132B within base 130B. Furthermore, the user have the bandwidth scheme automatically step down by requesting fewer parameters from the pod 132B.

The POD Mechanical Layout and Display

[00122] As stated before the pod is a detachable component of the defibrillator. It is generally stored within a receiving portion of the defibrillator but may be detached and carried to the emergency site, where it is used to monitor various medical parameters of the patient. The pod communicates information to the defibrillator either electrically or wirelessly. Typically, electrical communication is used when the pod is stored within the

defibrillator and wireless communication is used when the pod is detached from the defibrillator.

[00123] When communicating electrically, the defibrillator and pod are connected through electrical connections. In certain embodiments, the electrical connections comprise one or more leads connecting the defibrillator to the pod. In other embodiments, the electrical connections comprise direct electrical contact between the defibrillator and pod. For example, the pod may be stored within the defibrillator in such a way that each of their electrical components is in direct contact with each other. This direct electrical contact can be used for exchanging data or for recharging the pod battery.

[00124] When communicating wirelessly, the defibrillator and pod communicate via a wireless link. Typically, wireless communication is used when the pod is detached from the defibrillator. However, wireless communication can also be used when the pod is stored within the receiving portion.

[00125] The pod typically includes a display. The display can be used to display information that medical personnel may need while monitoring and/or delivering therapeutic functions to the patient at the emergency site. The display is primarily used for displaying patient information. For example, the display may be used to display current and historical patient data.

[00126] With reference to Figure 1C, an illustration of a pod display according to one embodiment of the invention is shown. In this embodiment, pod 811C has a small display 813C with a limited user interface. As shown, the pod display 813C includes an ECG monitor 815C for displaying primary waveform information, a control 817C for activation of the pod 811C, a control 819C, a 12-lead control 821C and a warning signal 823C. In certain preferable embodiments, the control 819C is a non-invasive blood pressure (NIBP) control, which allows the medical personnel to initiate a blood pressure reading. Likewise, 12-lead control 821C allows the medical personnel to initiate a 12-lead monitoring session. The warning signal 823C serves to warn of events such as a communication failure between the pod and the defibrillator. Additionally, there are one or more status lights 825C located on the pod display 813C. The lights 825C, e.g., preferably Light Emitting Diodes (LEDs), are preferably used as indicators for the pod, involving such parameters concerning the battery, the connection quality, the pod location, etc.

[00127] With respect to Figure 2C, an illustration of a pod display according to another embodiment of the invention is shown. In this embodiment, pod 827C has a pod display 829C including a screen 831C for monitoring various patient parameters, for example monitoring primary waveform information. Screen 831C also contains a battery status indicator 833C. Battery status indicator 833C displays the current power level of pod batteries 835C. Pod batteries 835C are positioned in electrical contact within pod 827C. Pod display of Figure 2C also includes a serial port 837C, a control 839C for powering on and off pod 827C, a warning signal 841C, and a speaker 843C. Warning signal 841C serves to warn of events such as a communication failure between pod 827C and the defibrillator as discussed above. Speaker 843C sounds an alarm along with warning signal 841C to alert the medical personnel of warning events.

[00128] In many cases, it is desirable to protect the patient cables connecting the patient and the pod. The leads should remain connected to the patient at the emergency site and also while transporting the patient from the emergency site. Any accidental disconnection of the leads may cause a disruption in the monitoring and/or therapeutic processes.

[00129] With reference to Figure 3C, a side view of a pod according to one embodiment of the invention, showing the position of the connectors and handle is shown. In certain embodiments, the pod itself is designed in a manner so if an object accidentally contacts the pod, or if the pod is dropped, the connected leads will be protected. For example, a pod 846C is shown comprising a main unit 845C, a display 847C, one or more connectors 849C and a carrying handle 851C. Connectors 849C are located on the top portion of pod 846C and slightly below carrying handle 851C so if an object contacts the pod from the top, the object will make contact with handle 851C before it contacts connectors 849C. Likewise, if the pod is dropped so that the top makes contact with the ground, carrying handle 851C will make contact with the ground, thereby giving some protection to connectors 849C located below.

[00130] It is also desirable to ensure that the leads are connected to the patient and the pod in an organized manner. For example, anywhere between 1 to 12 or more leads may be connected to the patient and pod and it would be desirable to easily separate and/or untangle the leads. The present invention also provides for a lead separator for organizing and separating the patient leads.

[00131] With reference to Figure 4C, an illustration of a lead separator according to a preferred embodiment of the invention. Lead separator 853C contains holes or apertures 855C for receiving leads 857C. When leads 857C are secured within holes 855C, lead separator 853C may be slidably moved along the length of leads 857C, as opposed to being clamped in one position. As separator 853C slides along the length of leads 857C, leads 857C are separated in an organized fashion.

[00132] It is often desirable to have a carrying bag 859C for easily transporting the pod to and from the emergency site. A pod-carrying bag 859C is also desirable for protecting the pod, its connectors, and other components from the outside environment. Thus, the present invention also provides a carrying bag 859C for carrying the pod. Any suitable carrying bag may be used for carrying the pod.

[00133] With reference to Figures 5C and 6C, a perspective view of a pod carrying bag according to one embodiment of the invention is shown. In this embodiment, carrying bag 859C includes a pod compartment 861C for receiving a pod and a pod component compartment 863C for receiving components of the pod. Pod compartment 861C has a cutout portion 865C so the pod may be positioned in pod compartment 861C so certain of the pod's electrical components are openly accessible through cutout portion 865C. Further, shoulder strap rings 867C are secured to opposing sides of pod compartment 861C for receiving a shoulder strap.

[00134] Component compartment 863C comprises an expandable portion 869C and a formed shell 871C. Expandable portion 869C is connected to pod compartment 861C and comprises a plurality of accordion-like folds 873C. The accordion-like folds 873C are hinged together at a common hinge 875C. A formed shell 871C is connected to the expandable portion 869C at a point furthest from pod compartment 861C. Formed shell 871 comprises a durable material and serves to protect the pod components.

[00135] With reference to Figure 6C, a side view of the pod-carrying bag displayed in Figure 5C in a connected position with a defibrillator is shown. A pod 879C and carrying bag 859C may be positioned in electrical contact with a defibrillator 877. When a pod 879 is positioned within carrying bag 859, certain of the pod's electrical components are openly accessible through cutout portion 865C. Carrying bag 859C may be positioned upon defibrillator 877C so the pod's exposed electrical components are in direct contact with

electrical components of defibrillator 877C. This direct electrical contact can be used for exchanging data or for recharging the pod battery.

[00136] While a preferred carrying bag has been described in Figures 5C and 6C, it should be apparent any suitable carrying bag could be used. For example, the carrying bag may include any number of pouches or compartments for storing the pod and pod components. The pouches may also be expandable in design. The pouches may be opened and closed using any suitable mechanism. For example, the pouches may be opened and closed using zippers, Velcro fasteners, or magnetic fasteners. The pouches may also be comprised of several different shapes. The shapes can directly correspond to the shape of the pod itself.

[00137] Carrying bag 859C may be comprised of any suitable material. In some embodiments, the bag may be comprised of a cleanable material that is flexible, yet sturdy material, such as nylon, plastic, fabric, or any other like materials. In other embodiments, the bag may be comprised of a more rigid shell. A rigid shell is advantageous because it allows for the bag to stand in an upright position rather than sagging or bunching up. A rigid material also serves to protect the pod and module components within carrying bag 859C.

[00138] A typical pod carrying bag 859C will have means for carrying bag 859C. For example, carrying bag 859C may be carried by use of a shoulder strap or by use of padded handgrips. In preferred embodiments, a shoulder strap is used for carrying bag 859C. A shoulder strap may also be attached directly to pod 879C itself, without the use of a carrying bag 859C.

[00139] The shoulder straps may be attached to the carrying bag 859C in any suitable manner. For example, in some embodiments, as the embodiment shown in Figure 5C, the shoulder straps may be attached to carrying bag 859C through the use of shoulder strap rings. In other embodiments, reinforced double stitching and/or reinforcing patches may be used to attach the shoulder strap to the fabric of carrying bag 859C. The shoulder strap may be an adjustable strap, so that the user can adjust the strap for a best fit.

[00140] In preferred embodiments, as in the embodiment shown in Figure 7C, a shoulder strap 881C is provided including two straps 883C attached to the main body of the carrying bag and each having an end 885C with corresponding fasteners 887C secured thereto. It should also be apparent these two straps 883C could be attached to the pod itself, rather than to the carrying bag. Fasteners 887C are used to secure the ends 885C of two straps 883C

together, forming a single, connected shoulder strap. Any suitable fastening feature can be used to secure the ends of two straps 883C together. In preferred embodiments, fasteners 887C include quick release buckles.

[00141] With the present invention, it would also be desirable to provide a means for securing the pod to a patient gurney. It is desirable to secure the pod to a gurney for several reasons. For example, it is desirable to secure the pod to a gurney so that medical personnel have easy access to the module and corresponding equipment. In medical emergencies, time is of the essence and it is vitally important to have all necessary medical equipment and supplies, including the pod, readily on hand for use by paramedics, doctors and so on, while the patient is transported to and from an ambulance, emergency room, operating room or intensive care ward. Likewise, it is desirable to secure the pod to a gurney in order to prevent any movement of the pod relative to the patient, which may lead to disconnection of the leads connecting the pod to the patient.

[00142] As shown in Figure 8C, a typical gurney 889C includes a mattress 891C resting atop and/or fastened to a supporting surface 893C. Supporting surface 893C is generally mounted atop an adjustable frame 895C. Wheels 897C are typically provided on adjustable frame 895C to allow gurney 889C to be pushed or pulled along the ground. Running between corresponding corners of a front portion 899C and a rear portion 901C of the gurney 889C are two side rails 903C (only one is visibly shown), typically mounted atop the supporting surface 893C. In certain preferable embodiments, the gurney 889C is adjustable as illustrated in Figure 9C. The part of the supporting surface 893C on the front portion 899C of the gurney 889C preferably can be raised or lowered. In turn, the patient respiratory region is subsequently elevated, making monitoring therefrom easier to set up and making treatment thereto easier to administer. As such, a pod 904C can be operatively coupled below the raised portion of the supporting surface 893C, or a pod 904C' can be operatively coupled above the rigid portion of the supporting surface 893C, or a pod 904C'' can be operatively coupled below the rigid portion of the supporting surface 893C. Such coupling is preferably provided through the use of appropriate brackets (not shown) which secure the pod to the gurney 889C in these various positions. Alternatively, the pod could likewise be coupled to the rear portion 901C of the gurney 889C when applicable. By being located in

any of these positions, the pod is made more accessible for the paramedic (i.e., easier to view and make changes) during monitoring or treatment of the patient.

[00143] In some embodiments, the pod can be positioned alongside the patient on the gurney mattress. In other embodiments, the pod can be placed on the patient himself. For example, Figure 10C shows a pod 905C placed on a patient 907C. Pod 905C includes two side flaps 909C attached to opposing sides of pod 905C. Side flaps 909C each include an internal pouch 911C for carrying components of pod 905C. When pod 905C is not positioned on top of a patient 907C, each side flap 909C may be folded over the top of pod 905C so the side flaps 909C overlap one another and so the internal pouches 911C are not visible. The overlapped side flaps 909C may be held together in overlapped position via Velcro strips, snaps, or any other attachment mechanism. In certain embodiments, one side flap may be longer than the other side flap so it can easily overlap the other side flap.

[00144] When it is desired to position pod 905C on patient 907C, two side flaps 909C are separated and folded downward over the body of patient 907C in a manner as displayed in Figure 10C. When side flaps 909C are in this folded downward position, pod 905C is stabilized on patient 907C and inner pouches 911C are visible.

[00145] While it is perfectly suitable to place pod 905C on top of patient 907C, it is often desirable (and sometimes necessary) to position pod 905C in proximity to patient 907C but not on top of or along with patient 907C on the gurney mattress, as mentioned above. For example, many ambulance gurneys are relatively compact so they may fit within an ambulance or transport helicopter and allow sufficient room for medical personnel to attend to patient 907C during transport. As a result, there is often not enough room for pod 905C to be placed on the gurney mattress.

[00146] In addition to mounting the pod onto the supporting surface 893C of the gurney as described above, the pod may also be positioned about one of the rails of the gurney. In certain embodiments, as in Figure 11C, a shoulder strap secures the pod or pod-carrying bag to a gurney rail. In other embodiments, as in Figure 11C, a holding tray is provided on a gurney rail for holding the pod.

[00147] In Figure 11C, a shoulder strap 913C is provided for securing a pod or pod carrying bag to a gurney rail 915C. Like the shoulder strap described in Figure 7C, shoulder strap 913C includes two straps 917C attached to the main body of the carrying bag or pod and

each having an end 919C with corresponding fasteners 921C, e.g., quick release buckles secured to each end. When it is desired to secure the pod or carrying bag to a gurney rail 915C, the paramedic can strap wrap the unconnected straps 917C around a gurney rail 915C and connect them together via the fasteners 921C.

[00148] In Figure 12C, a holding tray 923C is provided for securing pod 925C and/or pod carrying bag to a gurney 927C in methods already mentioned or similar methods. Pod holding tray 923C typically includes a tray having dimensions slightly larger than the dimensions of pod 925C and/or pod carrying bag. Any dimensions can be used so long as pod 925C and/or pod-carrying bag is comfortably received within tray 923C. In Figure 12C, pod holding tray 923C is secured to a foot rail 929C of the gurney. However, holding tray 923C may also be secured in any suitable position about a gurney, as mentioned above. For example, holding tray 923C can be secured to any of the gurney rails. Additionally, tray 923C can be secured in a position above or beneath the supporting surface of the gurney.

[00149] In some embodiments, the holding tray is detachably secured to a gurney so a paramedic may attach tray 923C to a gurney when needed. In other embodiments, the tray is permanently secured to a gurney so no attachment/detachment of the tray is needed. Holding tray 923C can also include support straps for firmly gripping pod 925C and/or pod carrying bag within tray 923C. Tray 923C may also be provided with one or more bumper pads around its edges to protect the patient and medical staff from injury if the tray is accidentally bumped into.

Interaction and Data Management of the POD/Defibrillator/Monitor

[00150] In broadening our invention scope, the focus of concentration is now shifted from the defibrillator-monitor and pod to other components interacting, and preferably transmitting information, with one or both of these devices. In certain embodiments, these other components either exist as modules removable from the defibrillator-monitor, or exist as devices independent of the defibrillator-monitor. As mentioned above, emergency personnel, when aiding patients suffering from cardiac related incidents, use the defibrillator-monitor and the pod. When aiding a patient in the field suffering from a cardiac condition, an emergency responder generally transports medical equipment (which may include either the defibrillator-monitor or pod or both) to not only aid, but also monitor, the patient at his

specific location. Unfortunately, this act of transporting can be unduly burdensome to the responder given the weight and size of the equipment as a whole. By incorporating a form of wireless communication between the defibrillator-monitor and the pod, as well as between the defibrillator-monitor and/or pod and some other desired equipment, both the responder and patient can benefit.

[00151] One piece of equipment the emergency responder typically transports to the field to aid the patient suffering from the cardiac related incident is an external defibrillator 100D, as shown in Figure 1D. In preferable embodiments, external defibrillator 100D includes a base 102D. Generally, base 102D includes a display 106D, a pod 108D, bays for defibrillator paddles (not shown), a power supply (not shown), a battery charger 110D, a keyboard 112D, a printer 114D, a mechanism for cellular communication 116D, a processing unit 118D, and a control panel 120D including one or more interfaces from which the user can select parameters involving, among other things, operation, patient parameter display, and pacing. As such, base 102D provides a number of bays for accommodating the modules. Additionally, other embodiments may exist in which external defibrillator 100D includes an AED module 104D or additional pods 108D having varying levels of functionality.

[00152] In the present embodiments, there are three potential modes of connection between base 102D and the modules housed therein (e.g., pod 108D, printer 114D, etc.) which can be provided. The first mode involves a direct connection, where the modules are docked directly to base 102D, and their connections are utilized for power as well as for communication purposes. The second mode also involves a direct connection, however, the modules are removable from base 102D, yet still connected thereto using cable, such as tethered cable 46A discussed in detail above. As such, the cable is again utilized for power as well as for communication purposes regarding the modules. In summary, the first two connection modes have similar electrical representations, but different mechanical representations. Using preferable embodiments of the invention, the third mode involves a wireless connection between base 102D and the modules. As such, the wireless connection is utilized for two-way communication between base 102D and each of the modules. Therefore, the modules are generally powered by a source other than base 102D, such as a battery. The wireless communication involves radio frequency (RF), infrared (IR), or other

similar wireless communication techniques, which are widely known to skilled practitioners in the art.

[00153] One preferable embodiment of the wireless communication mentioned above involves the means to automatically monitor the removal and/or usage of the removable modules housed in base 102D that are used to treat or monitor a patient. Preferably, base 102D detects and logs an event (into internal memory) once one or more modules are removed from or returned to base 102D. As such, base 102D subsequently tracks the event (i.e., using date, time, and specific module information). In certain embodiments, base 102D alerts the operator (e.g., using a visual or audible signal) when one or more modules are missing, and identifies and reports when one or more modules are returned to a wrong base station. The logging preferably reveals which modules are being used and their overall frequency of use. As such, the information is, in turn, used to provide insight as to the condition or status of the modules and the base 102D, and when calibration of the modules and base 102D is warranted.

[00154] In regard to the removable modules accommodated by base 102D of external defibrillator 100D, certain modules are described below. As discussed above, AED module 104D may be optionally utilized with and extracted from base station unit 102D for quick deployment in the field. AED module 104D may optionally include a small display (not shown) for the responder to view when used remotely from base station unit 102D. Alternatively, processing unit 118D, e.g., a PDA (Personal Digital Assistant) may further be detached from base station unit 102D and used to provide a display (not shown) for AED module 104D. As such, the processing unit 118D could further be used for diagnosis purposes, wherein a responder may administer a defibrillation shock to a patient based on data shown on unit 118D.

[00155] Pod 108D is removable from base station unit 102D, and is preferably capable of wirelessly interfacing with base 102D, and capable of wirelessly interfacing with AED module 104D independent of the base 102D, as represented in block diagram form in Figure 2D. In certain embodiments, pod 108D has the capability to monitor parameter data of a patient 121D, however, other preferable embodiments exist in which pod 108D stores patient data in memory to ensure no data is lost if the patient parameter is out of wireless range of either AED module 104D or computer 118D. Further, processing unit 118D mentioned

above preferably includes means to control AED module 104D, pod 108D, a camera (not shown), and an audio recorder (not shown). As such, the unit 118D could trigger a defibrillation shock to be administered to a patient based on its own diagnosis.

[00156] Any of the removable modules accommodated by base 102D may be configured to wirelessly communicate with one or both of base 102D and pod 108D. For example, printer 114D could be removed from base 102D and used to wirelessly communicate with base 102D or pod 108D or both in generating printouts of the patient parameters or status. Another example is the keyboard 112D, which is used as a means for data entry (in which patient name and other appropriate information is entered). The entered data is wirelessly transmitted to one or more of base 102D and pod 108D, and is preferably used for identifying and verifying data in wireless communications between base 102D and pod 108D, as well as other peripheral devices independent of the external defibrillator 100D. Further, by making the connection wireless between the modules, such as printer 114D or keyboard 112D, and base 102D, one could preferably eliminate the standard inclusion of some of the modules with base 102D. As a result, base 102D would have a reduced weight as well as a reduced cost for the consumer.

[00157] Preferably, in embodiments involving cardiac related incidents, pod 108D is generally removed from base 102D of the external defibrillator 100D and transported to the patient. As described above, pod 108D would generally maintain wireless communication with base 102D, as represented in Figure 2D. It is fully contemplated pod 108D and AED module 104D could be configured into a single device without departing from the spirit of the present invention. As such, when circumstances dictate such (i.e., the data collected from pod 108D necessitates that a defibrillation shock be administered), pod 108D would administer the shock following instruction from the base 104D. However, in certain preferable embodiments, pod 108D is primarily used to strictly monitor patient parameter data during pacing therapy (provided by the responder with base 102D) and is configured to automatically transmit the data in real time to base 102D in a wireless manner. It is contemplated, instead of pod 108D, the electrode sensors (not shown), which are generally attached to the terminal points of pod 108D and further attached to the patient, could be configured to wirelessly transmit data automatically to base 102D. However, this would be limited to transferring only ECG data and could typically not include other complex data,

such as pulse detection information. Base 102D is configured to wirelessly receive the data, provide cardiac therapy based on the content of the data, log and display the transmitted data on the physical display 106d (Figure 1D), as well as automatically transmit the data in real time to other devices when necessary. Generally, the transmitted data includes such information as paramedic data, the generated patient parameter data (e.g., pacing therapy, pertinent waveform information, etc.), and time synchronization.

[00158] In certain embodiments, an Electric Patient Care Report (ePCR) device 122D is also utilized, as referenced in the block diagram of Figure 2D. Preferably, ePCR device 122D is a PC tablet, or a notebook-type PC, and is used for entering patient data, generating patient reports, storing the patient parameter data, and providing a more advanced user interface for analyzing the patient parameter data. ePCR 122D is preferably configured to wirelessly communicate with base 102D. As such, the transmitted information wirelessly received by base 102D from pod 108D is automatically transmitted to ePCR 122D in a continuous manner (i.e., in real time). Preferably, ePCR 122D either contains, or has access to a remote database containing patient historical information, e.g., age, gender, allergies, which can be retransmitted to the medical responder. Presently, collection of such information by base 102D or ePCR 122D would generally involve either transporting the devices on-site to simultaneously collect and analyze the information, or data-dumping the entire set of information during post-episode. With the wireless transmission and automatic transferring of such information as described above, the need to transport such equipment to the patient or to data-dump during the post-episode is eliminated. Without the implementation of any diagnostic software therein or without the analysis of a third-party, ePCR 122D is used primarily for gathering, displaying, and storing patient parameter data for later downloading. However, given such software or operator, ePCR 122D is utilized for providing diagnosis in a timely fashion following an analysis of the transmitted patient data (e.g., using algorithms made available via ePCR 122D). In essence, the application for the invention is expanded with the wireless and automatic transmission between the units because ePCR 122D can be utilized interactively, in terms of analyzing and assisting with diagnosis and treatment, during the cardiac episode.

[00159] In certain embodiments, base 102D and ePCR 122D (or other such remote monitoring devices) are able to fully display an episode of a cardiac related incident. In

contrast to prior solutions when data-dumping was necessary in transmitting patient parameter data, the continuous wireless transmission of the data allows for more than just a specific waveform or data to be displayed. With the streaming continuity of the transmitted data, entire episodes are caught and fully displayed on the monitor devices. Similarly, digital cameras or video-enabled cellular phones (referenced in Figure 1D as part of 118D and 116D, respectively), either wired (using a USB) or wireless (using Bluetooth technology), provide the ability to capture video, and subsequently transmit from base 102D to monitor devices, as mentioned above. In both applications, the full display of the episodes or the videos can be annotated with patient information, time stamp, etc.

[00160] While one embodiment is described above with respect to ePCR 122D, it is contemplated that ePCR 122D may also be embodied in different fashions without departing from the spirit of the invention. For example, ePCR 122D may perform certain functions (e.g., monitoring) that are normally performed by base 102D. Additionally, ePCR 122D could exist as a module to base 102D, even though, similar to AED 104D, it is preferably embodied herein as an independent third-party product. Further, in lab applications, where ePCR 122D is kept in the same room or possibly in a nearby room, a wire connection could exist between ePCR 122D and one or more of pod 108D and base 102D, even though wireless connection had only been described above. Finally, while pod 108D and ePCR 122D are referenced above as interacting (i.e., transmitting information) via base 102D in routing patient parameter data, it is contemplated pod 108D could also be configured to directly transmit the data to ePCR 122D, or any other monitoring device (e.g., a PC) that uses requisite software without departing from the spirit of the invention. In turn, by having ePCR 122D and pod 108D in wireless communication, base 102D would mainly serve as a charging unit, a housing to physically secure the modules therein, and a cardiac therapy provider.

[00161] It should be appreciated base 102D is an autonomous unit, and as such, could be configured with built-in ePCR capability. As such, base 102D would have increased processing power. In turn, computer-aided dispatches could be wirelessly transmitted or received via base 102D. Further, added functionalities normally associated with ePCR 122D could include having direct access to patient information, having a means for logging events, being able to provide incident reports, and being able to access and provide billing records.

However, such an implementation to base 102D would cause it to be larger as well as more costly, which would negatively impact the consumer as well as the emergency responder.

[00162] In certain embodiments, a treatment module 124D is used with base 102D, as also represented in the block diagram of Figure 2D. Treatment module 124D is configured to wirelessly communicate with base 102D, and as such, is used to provide cardiac therapy, e.g., Cardio-Pulmonary Resuscitation (CPR), to the patient. For instance, one therapy preferably given by treatment module 124D is providing chest compressions. By having treatment module 124D wirelessly connected to base 102D, one would be able to coordinate the CPR treatment with the electric therapy, i.e., defibrillation, if necessary. Normally, when performing CPR on a patient, if the patient's heart is not responding, a defibrillation shock will be applied to the patient. Generally, any delay between providing the shock after the stoppage of the CPR is likely to decrease survival rate of the patient. Unfortunately, there is typically some delay involved in getting the paramedic clear of the patient. Presently, there is not an automated way of immediately administering the defibrillation shock after stoppage of the CPR treatment without potentially shocking the emergency paramedic. By using treatment module 124D, it is possible to coordinate these therapies so the defibrillation shock is given immediately after the stoppage of CPR treatment. As a result, with the reduced time delay, the survival rate for patients would likely increase. It is further appreciated that treatment module 124D could be used either in conjunction with or in place of pod 108D.

[00163] In certain embodiments, a defibrillator 126D currently in use by a patient 121D, is wirelessly connected to base 102D, as further represented in block diagram form in Figure 2D. As such, base 102D wirelessly receives the patient ECG data from defibrillator 126D. As such, base 102D further processes the waveforms to verify whether defibrillation is necessary. Additionally, base 102D can alert defibrillator 126D in advance of a shock being administered so circuitry can be switched out to prevent damage. Further, base 102D can be used to forward the data received to the hospital for further analysis. Finally, with the ability to relocate waveform processing, defibrillator 126D can be made smaller and less costly in the future.

[00164] While it is mentioned above, pod 108D may have a wireless connection with ePCR 122D, in other certain embodiments, pod 108D may also wirelessly communicate with a remote access point 128D, independent of base 102D, as represented in block diagram form

in Figure 3D. As such, patient parameter data would be transmitted from pod 108D to remote access point 128D, which is further connected to a continuous monitoring system 130D. Presently, pod 108D transmits the patient parameter data, i.e., signal acquisition data, primarily to base 102D, without any further processing any of the data. The additional processing performed is typically provided further down the transmission line stream. However, with pod 108D utilizing remote access point 128D instead of base 102D as its funnel point for data, additional processing of the patient parameters could now be provided by pod 108D before transmitting the data. As a result, the data transmitted via remote access point 128D would already be configured. In turn, the data ending up at the continuous monitoring system 130D would need no further manipulation and could be immediately monitored, analyzed, and/or stored. As a result, any delay caused by processing the data during post-transmission is eliminated. Further, more time is provided for diagnosis. In addition, one or more pods 108D could be configured to communicate with remote access point 128D so one or more sets of patient parameter data could be wirelessly transmitted. This would be a departure from the industry standard ratio of generally having only one pod in communication with one device (i.e., generally a base paired to the pod).

[00165] While it has been described above that one or more pods could be utilized to wirelessly communicate data to a remote access point 128D, a similar practice could involve base 102D. However, as represented in block diagram form in Figure 4D, base 102D would preferably be wirelessly transmitting the patient parameter data from inside an ambulance, and the access point would be a clinical information system (CIS) 132D located at a hospital, which is further connected to an LNRS 134D. This transmission would occur automatically when base 102D was within reasonable transmission range of CIS 132D, preferably before the ambulance arrived at the hospital with the patient. Similar to the wireless transmissions to ePCR 122D (Figure 2D) and remote access point 128D (Figure 3D) described above, the transmission to CIS 132D would occur automatically, without further user intervention. Alternatively, the data could be wirelessly transferred from base 102D to the hospital via cellular communication mechanism 116D, i.e., a cellular phone (referenced in Figure 1D). As such, the data would be transmitted to a cellular transmission tower 136D, and in turn, to a wide area network (WAN) 138D accessible to CIS 132D. While this method could be implemented using packet-based data transfer, it still involves a delay in data transmission as

well as a generally more expensive method of data transfer. Normally, the data is downloaded only after the patient has already arrived at the hospital; well after the episode has taken place. In wirelessly transmitting the patient parameter data ahead of arrival via an access point 130D or even via cellular phone, physicians at the hospital would have more time to access the data and prepare a diagnosis and possible treatment for the patient being transported to the hospital.

[00166] In certain embodiments, communications can be made to and from base 102D for a variety of items, ranging from health status of the modules and base 102D to software upgrade for base 102D. In regard to the health status of the modules and base 102D, messages are wirelessly transmitted away from base 102D. The process is depicted in the flowchart of Figure 5D. As such, base 102D may be automatically configured (e.g., via a timer circuit) in state 140D or may have to be manually prompted (e.g., via a wireless card) in state 142D in order to perform a self-test. Base 102D may rely on a number of methods for self-testing the devices in state 144D. A few examples are tests based on recommended service periods in testing the devices (e.g., base 102D, pod 108D, etc.) or tests based on expiration dates for components (e.g., batteries) used in powering the devices. Based on the results of the self-test, base 102D may notify a technician in state 146D via cellular phone 116D if one or more units needs or will need service. Alternatively, base 102D may update the customer in state 148D on a nightly basis as to the current health status of the one or more units. In regard to the software upgrade for base 102D, messages are wirelessly received by base 102D. As such, the upgrade can also be initiated automatically (e.g., via phone lines directly connected to the device) or manually (e.g., via a PC connected to a web browser). In doing so, hardware and software compatibility can be checked and verified. Additionally, using these same techniques, base 102D or the modules can be retested after having been shipped to verify proper functioning.

[00167] In reference to the self-test example mentioned above in which expiration dates are monitored for batteries, it is contemplated smart batteries may be used to track pods 108D for service notification or supply renewal. The information, which can be tracked, includes unit type, unit identification number, and unit serial number. As such, the results of the tracking process can be additionally included as a part of the base unit service log communicated to the customer on a nightly basis.

[00168] In certain embodiments, the wireless system referenced herein regarding external defibrillator 100D (Figure 1D) is used for in-service demonstrations and training for emergency personnel, as referenced in the block diagram of Figure 6D. The demonstrations and training sessions are protocol-based, PC-simulated, and could be provided automatically or by remote control. In summary, PC 150D would be used to run software configured by a trainer, and the software would be used to control a device, for example, a pod 108D wirelessly linked to one or more base stations 102D. As such, each of the trainees would be trained on one of these base stations 102D. Preferably, the trainees would be quizzed on proper use of base 102D given a certain emergency scenario, e.g., in reference to a particular pod 108D patient set-up or a particular data output on the monitor. In turn, the trainees would be timed and scored on their responses. As such, the PC-simulated demonstrations or training could also be used in the field when emergency personnel are not active in duty.

[00169] In certain embodiments, emergency responders still desire to transport the external defibrillator 100D (referenced in Figure 1D) in order to be able to rely on more information for diagnostic and treatment purposes. Even in such embodiments, the wireless aspects of the invention still have application. Presently, a responder would generally need to look away from the patient to analyze the patient parameter data on the display 106D of base 102D (Figure 1D), or some other portable monitor. However, the wireless aspects of the invention alternatively allow the responder to view the data using a more convenient display medium. Such medium would be configured to wirelessly receive the data from pod 108D via base 102D. Preferably, in using such medium, the data would be within the responder's line-of-sight at the same time he is viewing the patient. A couple examples of such a medium include glasses or a headset, i.e., one-eye display with ear clasp as shown in Figure 1A. Likewise, it is contemplated other compact medium, similar to the glasses and headset, could alternatively be used in displaying the patient parameter data wirelessly received from base 102D. This embodiment would preferably require the use of a portable processing block or unit that could be carried or strapped to the responder personnel. It is appreciated the quantity of data wirelessly transmitted between base 102D and the compact display medium may be limited for bandwidth considerations. As such, the processing block would be an intermediate processing mechanism between base 102D and the display medium to aid in reducing the amount of data transferred from base 102D. It is also appreciated while the

responder uses the compact medium for receiving information for base 102D, the medium could be further configured to transmit information back to base 102D based on the data analysis of the responder. This could be provided by having base 102D configured to interpret operator voice requests wirelessly transmitted from the compact medium. Further, base 102D could be configured to wirelessly transmit voice prompts to the responder in response to the requests or for need of a prompt from the responder regarding a different matter.

The Defibrillator/Monitor Mechanical Layout and Display.

[00170] The invention is also directed to an external defibrillator with a tiered alarm-reporting scheme. This scheme may be programmed to delineate between critical faults, non-critical faults, and other routine diagnostic reminders or test reports within the defibrillator device. The fault detection is directed toward the primary user of the defibrillator. For example, a high impact fault may be one where the defibrillator is unable to deliver proper therapy to the patient due to some internal anomaly. This type of alarm would report and demand immediate attention from the primary user. A lower impact fault conversely may simply alert the user to the condition and record the fault information so it is available for subsequent troubleshooting.

[00171] One example of a fault is sporadic communication degradation within the unit. These types of transient situations would be lower level alarms that would be logged with a diagnostic code for later evaluation by a service person. Service personnel can use trends in these types of lower level alarms to perform predictive and preventative maintenance on the device, but the tiered system prevents these somewhat minor transient alarms from becoming a nuisance to the primary operator of the defibrillator. Dropped messages on serial ports or watchdog timer timeouts are examples of lower level faults which, if they occur with a high or increasing frequency, may indicate imminent hardware failures which can indicate the need for preventive hardware replacement.

[00172] The defibrillator may be configurable in either an ALS mode or an AED mode. The ALS mode includes a multi-parameter monitoring capability and all of the defibrillator therapy delivery capability. The AED function may be contained in the separable pod, which may be removed from the base unit for ease of transport. Additionally the base unit may be

configurable to act just as an AED. The tiering of the alarms can be included as an aspect of these alternative configurations so when the device is configured as an AED the display and monitor related alarms are given lower priority. Conversely when the device is configured as an ALS the priority of the critical monitor related alarms is increased. Of course, the user may decide they want all diagnostic faults annunciated regardless of the mode.

[00173] The defibrillator is also configurable based on the experience and training levels of the individual users. For example a novice user may want more help screens and prompting for performing the various protocols and operations of the device. A more experienced user may not want to wade through several help screens and may prefer shortcuts and higher levels of control of the machine. The various levels of user help can be pre-configured so the operator can enter a personal code into the unit, at the beginning of their shift, for example. Further, the level of feedback and prompting the operator prefers from the machine will be preset and available automatically. In this way the device “knows” the level of the operator’s proficiency and eliminates the need for the operator to customize the device to personal preferences each time a new operator begins to use the device.

[00174] Occasionally, emergency services providers prefer that waveforms indicating patient electrocardiogram activity not be displayed on the defibrillator monitor. This may be because the operator is not trained to interpret the waveform and the emergency service providers do not want the operators to be distracted by the waveforms or to attempt to modify treatment based on information they do not fully understand. The defibrillator of this invention may be configured to eliminate the waveform display. This configuration option may be integrated with the operator proficiency customization described above, but this is not essential to the present invention. Further the customization could be done for the base unit, the pod, or both.

[00175] Referring now to Figure 1E, an accessory container for use with this invention is shown in a perspective view. The container includes an upper strap 110E with a hook and loop fastener section 120E. Accessory container 100E also includes a lower retaining pocket 140E, which may be attached to accessory container 100E by stitching 150E or any means known in the art.

[00176] Figure 2E shows a side cross-section of the accessory container. Upper strap 110E is shown as fastened to the inside of accessory container 100E by stitching 150E or any

fastening means 160E known in the art. Upper strap 110E is shown exiting accessory container 100E through strap opening 130E and returning through strap opening 130E to the inside of accessory container 100E.

[00177] Figure 3E is an end view of an apparatus configured for use with the accessory container. The apparatus could, for example, be a portable defibrillator. The apparatus includes a modified shoulder harness bracket 170E, and accessory retention bracket 180E and a lower retaining insert 190E.

[00178] Figure 4E is a cross-section of an apparatus equipped with an accessory retention bracket and a lower retaining insert. To this is attached an accessory container 100E. This attachment is accomplished by sliding lower retaining pocket 140E over lower retaining insert 190E and passing upper strap 110E through slot 200E in accessory retention bracket 180E and then passing upper strap 110E back into accessory container 100E where it is attached via the hook and loop fastener 120E. In applications where the apparatus to which accessory container 100E is attached is a defibrillator device, accessory container 100E can be adapted to carry items useful to emergency medical technicians in the field. These items include but are not limited to diagnostic cables for the defibrillator, therapy cables for the defibrillator, scissors, tape, and other items commonly used in emergency medical treatment.

[00179] A larger accessory container 100E can be accommodated by using the modified shoulder harness bracket 170E to retain strap 110E in the same way as is described above relative to accessory retention bracket 180E. Referring to Figures 3E and 4E, lower retaining pocket 140E is slid over lower retaining insert 190E. Upper strap 110E passes through the shoulder harness slot 220E and then backs into accessory container 100E where it is secured via the hook and loops fastener 120E.

[00180] Figure 5E discloses a perspective view of the apparatus with the accessory retention bracket and lower retaining insert 190E. This figure shows in greater detail possible configurations of an apparatus with accessory retention bracket 180E and a lower retaining insert 190E attached to them. It is not intended to be a limiting disclosure of embodiments, but merely exemplary.

[00181] Figure 6E shows a cross-section of an apparatus with the accessory retention bracket and the lower retaining insert affixed. Again, this is merely an exemplary disclosure of a possible configuration, and not meant to be limiting in any way.

[00182] Figure 7E is a cross-sectional view of the modified shoulder harness bracket. Modified shoulder harness bracket 170E can be used to carry the apparatus by connecting a conventional shoulder strap or harness to the bracket via shoulder harness hole 210E. Modified shoulder harness bracket 170E can also be used in the same fashion as accessory retention bracket 180E to affix an accessory container 100E to the apparatus. Shoulder harness slot 220E performs the same function as slot 200E in accessory retention bracket 180E.

[00183] Accessory container 100E may be attached in the fashion described above to the main defibrillator unit or to a removable and portable defibrillator pod as described elsewhere in this application.

[00184] Figure 8E is a perspective view of the modified shoulder harness bracket showing the shoulder harness hole and the shoulder harness slot. This figure is an exemplary embodiment of modified shoulder harness bracket 170E and is not meant to be construed as a limiting configuration.

[00185] Figure 9E shows a perspective view of a securing bracket for a defibrillator paddle. Bracket 230E includes a raised portion around at least a portion of the perimeter to protect the paddle when the defibrillator unit is being carried or jostled about in an ambulance or during other use. Bracket 230E includes a latch 240E for securely fastening the paddle within bracket 230E and for easy removal from bracket 230E. Bracket 230E can be configured to incorporate an electrical or other contact with the casewall to allow for a paddle test while the paddle is retained within the bracket 230E. Bracket 230E may also include space for defibrillator wire leads or other related equipment to allow for secure storage of all of the removable components required for appropriate defibrillator operation.

[00186] Figure 10E shows an end view of a defibrillator unit 250E with a removable pod 260E. The defibrillator unit has an adjustable handle 270E with a set screw 280E.

[00187] Figure 11E shows the defibrillator unit with the pod and an accessory container attached to the pod as described above with reference to Figures 1E through 8E. Adjustable handle 270E has been rotated so the center of gravity indicated by the dash line is now directly under handle 270E in its new position. Set screw 280E is tightened to secure adjustable handle 270E in this position. In this manner adjustable handle 270E can be configured based on the weight distribution of the main defibrillator unit, the pod, and an

accessory container 100E so the unit when carried is in a substantially upright position and the weight is well balanced.

[00188] Figure 12E shows a perspective view of a gurney hook. Gurney hook 290E may be formed of any strong wire like material, and the embodiment shown is but one exemplary configuration. It may be formed in any shape which allows it to be conveniently hung on a bed bar or side rail of a gurney.

[00189] Figure 13E is a side view of the adjustable handle. Gurney hook 290E is shown attached to an end of a adjustable handle 270E. In this exemplary configuration, gurney hook 290E is convenient to the user of the defibrillator who, while carrying the defibrillator, can easily access the gurney hook and attach it to a gurney or bed rail while supporting the weight of the defibrillator by adjustable handle 270E.

[00190] Figure 14E is an end view of a defibrillator equipped with the adjustable handle and gurney hook. Gurney hook is shown as element 290EA in the neutral position where it would rest when the defibrillator is not being used or not being connected to a gurney or a bed rail. 290EB shows the gurney hook attached to a gurney rail as required when the gurney rail is supporting the defibrillator. Gurney hook 290E is attached to adjustable handle 270E in such a way that it can be rotated about its point of attachment from neutral position 290EA to the position where it can engage the gurney rail (290EB).

[00191] Figure 15E shows a perspective view of a defibrillator with an integrated display guard. Integrated display guard 300E protects the display in rugged environments and has vents for removing condensation. Display guard 300E provides access to keys through an access opening 310E. This allows the user to access soft touch or other keys located under display guard 300E near the display without removing display guard 300E. If scratched or damaged during use, display guard 300E can be replaced inexpensively.

[00192] Figure 16E is a cross section of the display guard showing its relation to the display screen. The space between display guard 300E and display screen 320E allows for deflection of the display guard 300E without resulting damage to the display screen 320E. The device can be designed with a recessed portion configured to accommodate display guard 300E so display guard 300E does not protrude from the rest of the defibrillator but rather looks and behaves like an integral part of the defibrillator casing.

[00193] Figure 17E shows a cross section of the display guard, which is connected to the apparatus by screws. Screw 330E also retains a bumper 340E which is oriented around the perimeter of the display guard. Bumper 340E provides further protection for display guard 300E itself during rough handling and in rugged environments in which the defibrillator may be used.

[00194] Figure 18E shows a bumper 340E secured to display guard 300E. Figure 19E also shows access opening 310E through which keys or other devices in the vicinity of the display may be accessed while the display guard is in place.

[00195] All of the embodiments shown of the display guard are merely exemplary, and other configurations will be obvious to those skilled in the art and are contemplated by this invention and disclosure.

Power and Battery Sharing Between Pod and Base Unit

[00196] With reference to Figure 1F, a pictorial display of a patient module and a defibrillator/monitor in a power-sharing embodiment of the present invention is shown. In the present embodiment, and as stated above, both pod 12F and base 10F have separate but interchangeable batteries (not shown). In a preferred embodiment base 10F has 2 batteries each of which is interchangeable with the pod's battery. Generally, the extra battery is needed to provide the necessary energy for defibrillation therapy as well as providing energy to pod 12F when necessary as will be discussed in more detail below.

[00197] Generally, upon power up both base 10F and pod 12F power up on their respective batteries. Moreover, pod 12F will remain on its own battery power in order to conserve the base's battery so base 10F will be able to provide defibrillation therapy to a patient when it is needed. As discussed above, base 10F will quickly establish communications with pod 12F to determine if pod 12F is docked in station 16F, tethered by cable 14F, or is remote using wireless communications. If pod 12F is docked or tethered, base 10F will communicate to pod 12F whether base 10F is connected to an external power source 18F. External power source 18F could be an A/C or D/C power source or even an A/C or D/C power supply such as the ones discussed in Figures 5A above. If base 10F is connected to external power source 18F, pod 12F will quit using its own battery and instead receive external power through base 10F. If base 10F is not connected to external power source 18F, then pod 12F will remain

using the energy of its own battery until it reaches a “low power” state. Upon reaching the lower power state, pod 12F will request a power transfer from base 10F through cable 14F. Upon the request, base 10F will transfer power through cable 14F unless base 10F has reached a low power state. If base 10F has reached a low power state, then base 10F will initiate an alarm informing the user that base 10F must be connected to external power source 18F or base 10F and pod 12F batteries must be replaced. It is contemplated there could be more than one tethered cable, such as one cable providing patient and/or pod data and another cable providing power without departing from the spirit of the invention. It is further contemplated the low power state for the base would be a power state above which a defibrillation therapy could successfully be provided to a patient. It is further contemplated if the pod is remote from the base and communicating wirelessly and experienced a low power state, the pod would then sound an alarm to the user informing the user the pod must be connected via the tethered cable or the pod must be docked so it can power share with the base.

[00198] Generally, battery-charging control is maintained by a power module (not shown) located in base 10F. The power module is able to determine when a battery needs charging, how long the charging will take, and how much energy it will take to charge the battery. In a preferred embodiment, the batteries in pod 12F and base 10F are “smart” batteries. The smart battery is able to communicate with the power module and provide the module with several variables providing the battery’s status, such as energy level, whether the battery is in use presently, the battery’s use over a time period, etc. It is of note pod 12F does not have a power module comparable to the power module in base 10F. Instead of duplicating the circuitry of the power module in base 10F, pod 12F contains power-multiplexing circuitry, which allows pod 12F to interrogate its smart battery and relay this information to the power module or it allows the pod’s smart battery to directly communicate with the power module. The power module would then directly interrogate the pod’s smart battery and retrieve the necessary information for charging. Further, the power module is isolated from the rest of the base circuitry so it can charge the batteries even when base 10F is turned off. This reduces the amount of circuitry needing power during the charging process, thus conserving energy.

[00199] With reference to Figure 2F, a schematic view of a defibrillator/monitor providing battery charging control of a patient module in an embodiment of the present invention is shown. When docked or connected by a tethered cable, base 20F establishes several connections to pod 28F through communication bus 30F, battery charging bus 46F, and power bus 45F. Power bus 45F provides power to pod 28F through base 20F when base 20F is connected to an external power source. In the present embodiment, base 20F is able to control the charging of batteries 22F, 24F, and 26F located within pod 28F. As discussed above, communication bus 30F and charging bus 46F allow base 20F to charge batteries 22F, 24F, and 26F and thus allows for only one power module 32F, which remains in base 20F, thus reducing the amount of circuitry needed. If base 20F is connected to an external power source, power is transferred to base 20F through battery lines 34F and 36F via an external or internal power supply. Power microprocessor 38F is continually interrogating batteries 22F, 24F, and 26F through communication multiplexer 40F, to obtain vital battery information such as voltage and current parameters, battery's charge level, and a battery serial number. Microprocessor 38F then determines two out of three batteries 22F, 24F, and 26F, which require charging based upon the interrogated battery information. Since base 20F has two independent power lines 34F and 36F, base 20F is able to charge two of the three batteries 22F, 24F, and 26F simultaneously. For example, module 32F could charge batteries 22F and 24F, or 22F and 26F, or 24F and 26F at the same time. Generally, batteries 22F and 24F are charged first so base 20F is quickly provided with the energy to provide defibrillation therapy. It is further contemplated any one of batteries 22F, 24F, and 26F could be charged by themselves. It is further contemplated all three batteries 22F, 24F, and 26F could be charged together without departing from the spirit of the invention.

[00200] Once processor 38F determines which two batteries need charging, power is routed through a switching matrix comprised of switches 42F and 44F to batteries 22F or 24F or through battery charger bus 46F to battery 26F. Processor 38F controls which batteries will be charged through power multiplexer 39F, which controls the switching matrix. Once a battery is fully charged, processor 38F then routes the power to the third and remaining battery in need of charging. When batteries 22F, 24F, and 26F are all fully charged, switches 42F and 44F are opened and the incoming power continues to power base 20F and pod 28F through power bus 45F.

[00201] When pod 28F is being used in a wireless mode, communication bus 48F is engaged by power processor 49F to route battery 26F information via signal processor 50F. Once the power processor 49F routes the information to signal processor 50F, the signal processor 50F processes the battery information and transmits all battery 26F information to base 20F. It is fully contemplated processors 38F and 49F could be any type of processor including a microcontroller or an ASIC (Application Specific Integrated Circuit) without departing from the spirit of the invention. Further, signal processor 50F can be any type of signal processor known to those with skill in the art. Base 20F uses the battery information to monitor the charge on battery 26F and displays this information on a monitor (not shown) as a fuel gauge, which is discussed in more detail below, so the user can easily monitor the status of the pod's battery 26F. Base 20F also uses this information to initiate an alarm on base 20F and/or pod 28F to alert the user the pod's battery 26F is depleted and pod 28F needs to be connected via a cable to base 20F or pod 28F needs to be docked with base 20F so battery 26F can be charged. Generally, pod 28F is turned off when it is charging. However buses 46F and 30F remain open so pod 28F can recharge battery 26F and be interrogated by base 20F to monitor the charging process.

[00202] With reference once again to Figure 2F, in another embodiment there is a power on and power off interaction between base 20F and pod 28F. If base 20F and pod 28F are in electrical contact either through a tethered cable or through pod 28F being docked with base 20F, a user could press an on/off button (not shown) on base 20F powering up base 20F and a signal would be sent from system control module 100F on system bus 102F to pod 28F instructing pod 28F to power up. If the user then desired to power down base 20F, they would then press the on/off button on base 20F powering down base 20F and a signal would be sent from system control module 100F on system bus 102F to pod 28F instructing pod 28F to power down. In an alternative embodiment, pod 28F would be able to detect base 20F had powered up by power being transferred across bus 45F and then pod 28F would power up itself. Upon power up of base 20F, system control module 100F establishes the initial condition of base 20F and pod 28F and coordinates communication of all modules. The control module 100F then confirms with processor 50F through control bus 102F the pod's power situation (e.g., pod 28F is running off battery 26F or is receiving power from base 20F through power bus 45F) and the pod's current power management.

[00203] Similar to base 20F, pod 28F has an on/off button (not shown) where a user can press the button and turn pod 28F on or off. If pod 28F is docked with base 20F and pod 28F is powered up, pod 28F will begin to interrogate communications with base 20F. If after a period of minutes pod 28F cannot establish communications with base 20F, then pod 28F would assume powering up was inadvertent and turn itself off to conserve battery power. In another embodiment, the user would be able to power up base 20F from pod 28F similar to powering up pod 28F from base 20F discussed above. Pod 28F can also be powered up from base 20F in a wireless mode. If pod 28F is remote from base 20F and a user powers up base 20F, base 20F will determine pod 28F is not directly connected to base 20F and then transmit an RF signature which when received by pod 28F would power up pod 28F. In addition, pod 28F could be powered down from base 20F as long as pod 28F is within transmitting range of base 20F. If communications between pod 28F and base 20F is lost, pod 28F will try to reestablish communications for several minutes. If pod 28F is unable to reestablish communications with base 20F, then pod 28F will power itself down to conserve battery power. However, if pod 28F came back within communication range of base 20F, then the RF signature from base 20F would power up pod 28F and base 20F would begin reestablishing communications.

[00204] With reference to Figure 3F, a schematic view of a defibrillator/monitor battery-charging scheme in an embodiment of the present invention is shown. External adapter 62F provides battery-charging circuitry for charging battery's 64F and 66F located within base 60F. External adapter 62F can be a docking station as discussed above with reference to Figures 8A or an adaptor as discussed above with reference to Figures 5A. In this embodiment, the battery charging circuitry has been removed from base 60F to reduce the cost of base 62F and to make base 62F lighter. External adapter 62F can receive power input from an A/C source 68F or a D/C source 70F or both; however, both are not necessarily needed together to stay within the spirit of the invention. If A/C source 68F is utilized, the power is first filtered through A/C filter 72F and then converted to 10-16V D/C by converter 74F. This voltage can then be routed to power module 76F where it is used to power base 60F and routed to boost converter 80F, which converts the power to 20V which is provided to battery charging circuits 82F and 84F. If D/C source 70F is utilized, the power is filtered by D/C filter 78F and routed to power module 76F where it is used to power base 60F and

boost converter 80F which converts the power to 20V which is provided to battery charging circuits 82F and 84F.

[00205] Communications bus 85F provides communication with power processor 86F, a pod battery (not shown) through multiplexer 88F. Bus 85F further provides communication with power processor 86F and battery chargers 82F and 84F through bus multiplexer 90F. Generally, bus 85F is an Inter-IC bus, however, it is fully contemplated bus 85F could be any type of bus known to those with skill in the art without departing from the spirit of the invention. Through communication bus 85F power processor 86F provides chargers 82F and 84F with the proper charging parameters, such as proper voltage, current, and charge time, based upon information interrogated from batteries 64F and 66F. Battery chargers 82F and 84F then use this charging parameter information to provide the correct charging voltage and current to power module 76F, which then routes this power to batteries 64F and 66F through battery circuit boards 92F and 94F. Therefore bus 85F allows processor 86F to parametrically control the charging of batteries 82F and 84F. This allows for the use of varying types of batteries as well as algorithms, which might change over time due to technology changes.

[00206] One skilled in the art will appreciate that the present invention can be practiced with embodiments other than those disclosed. The disclosed embodiments are presented for purposes of illustration and not limitation, and the present invention is limited only by the claims that follow.

ABSTRACT

[00207] The invention provides a fully functional ALS product with a separable external defibrillator. The external defibrillator includes a defibrillator/monitor and a patient monitor. The patient monitor is generally accommodated by the defibrillator/monitor. The patient monitor is removable from the defibrillator/monitor so as to be used remotely. The designs of the patient monitor and the defibrillator/monitor enable both to be used in a variety of applications. These applications provide benefits for the medical responder and the patient.

#2832690\3

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Problem Image Mailbox.**

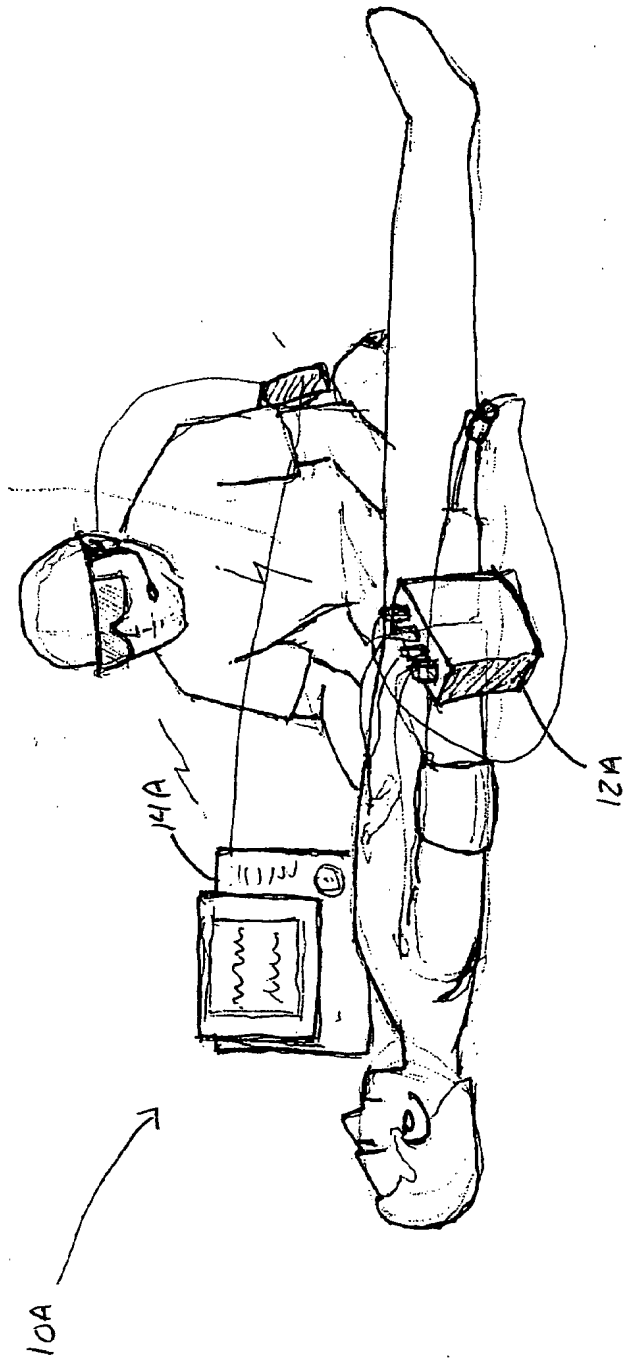


Figure 1A

15A

CC2
Monty latches
to main unit-

- guide ribs
control motion
in two directions
and align with
connector

- latch actually
automatically
when Monty
drops in.

- latch operates
with one hand
(same one lifts
Monty out?)

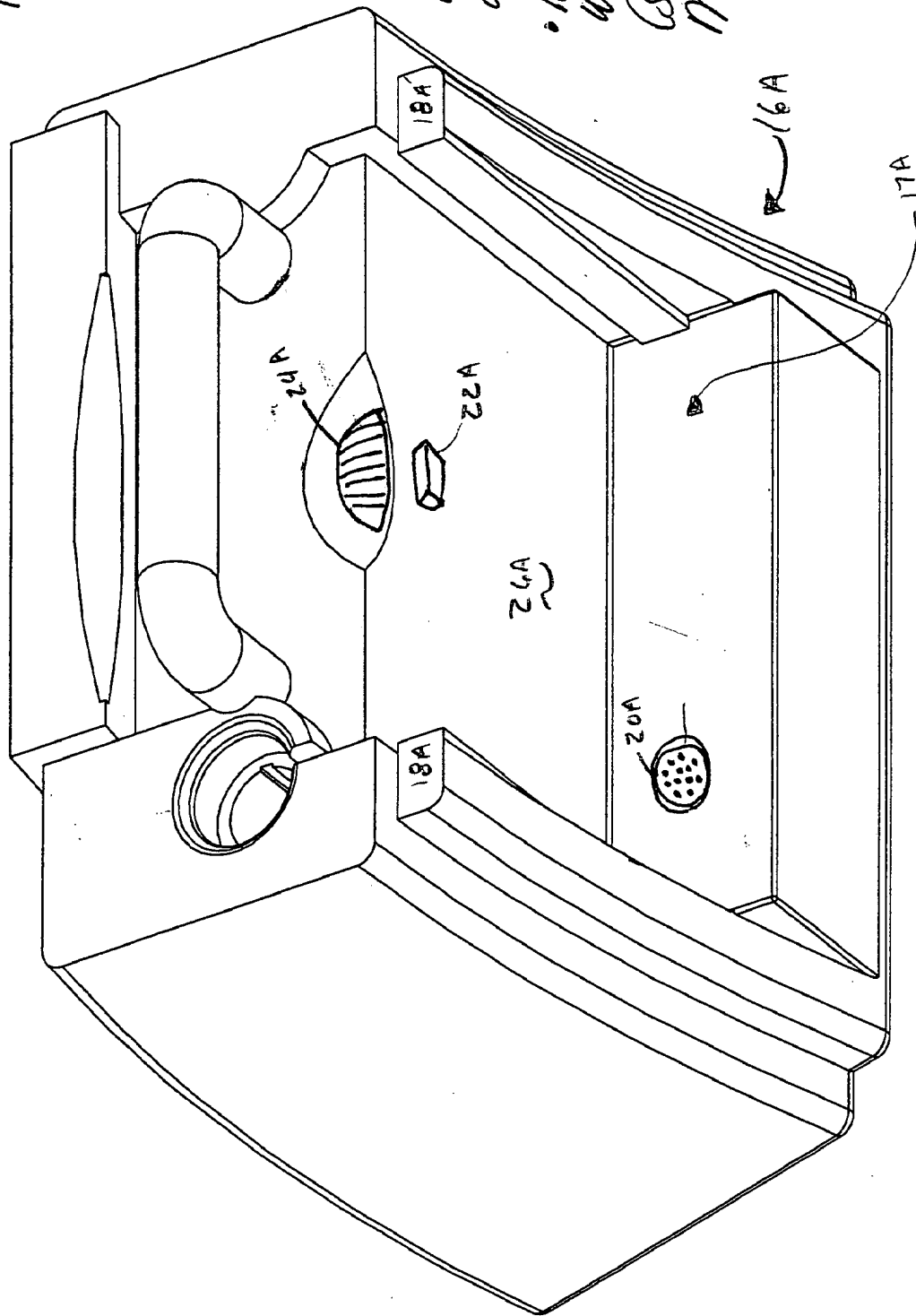


Figure 2A

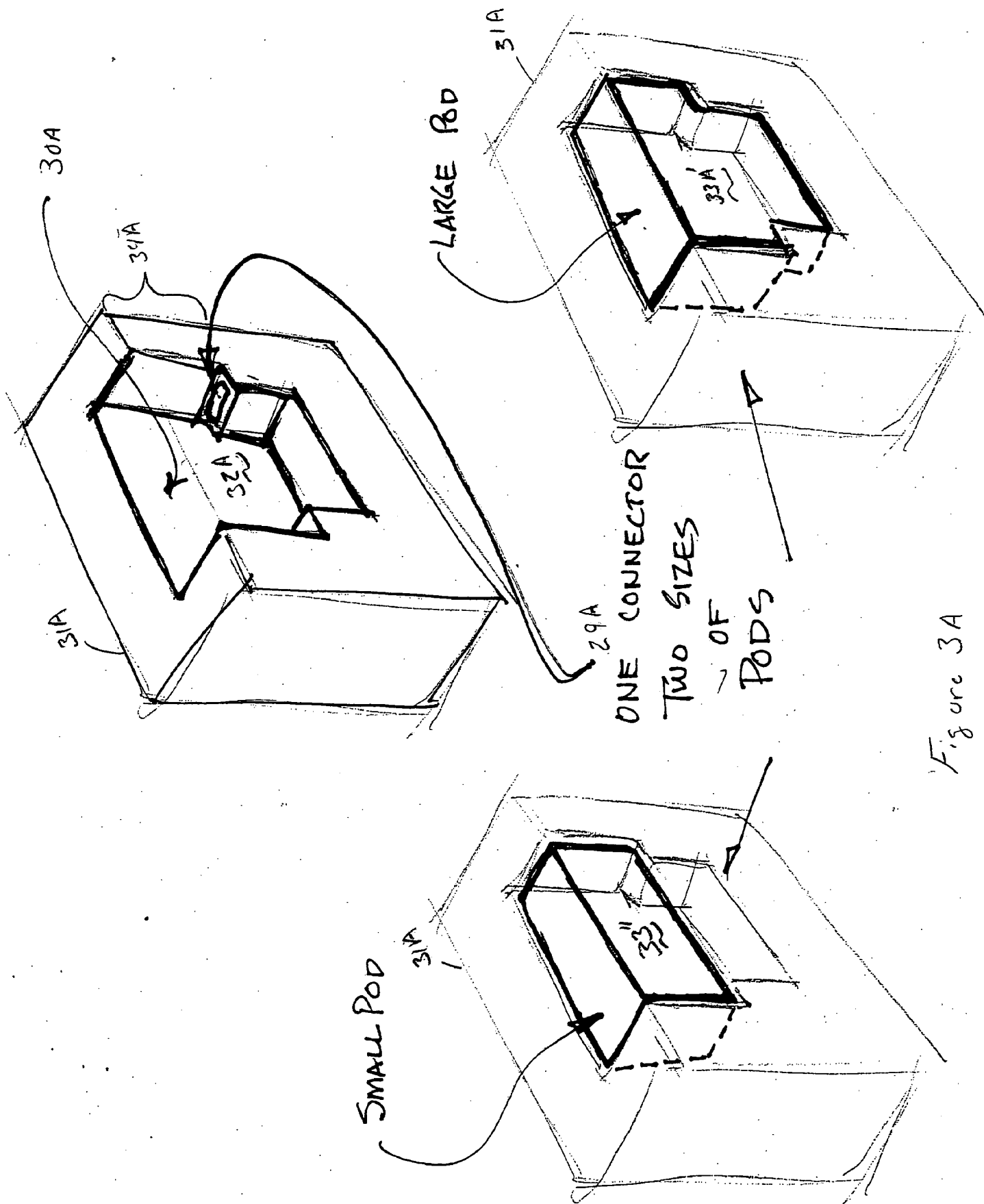
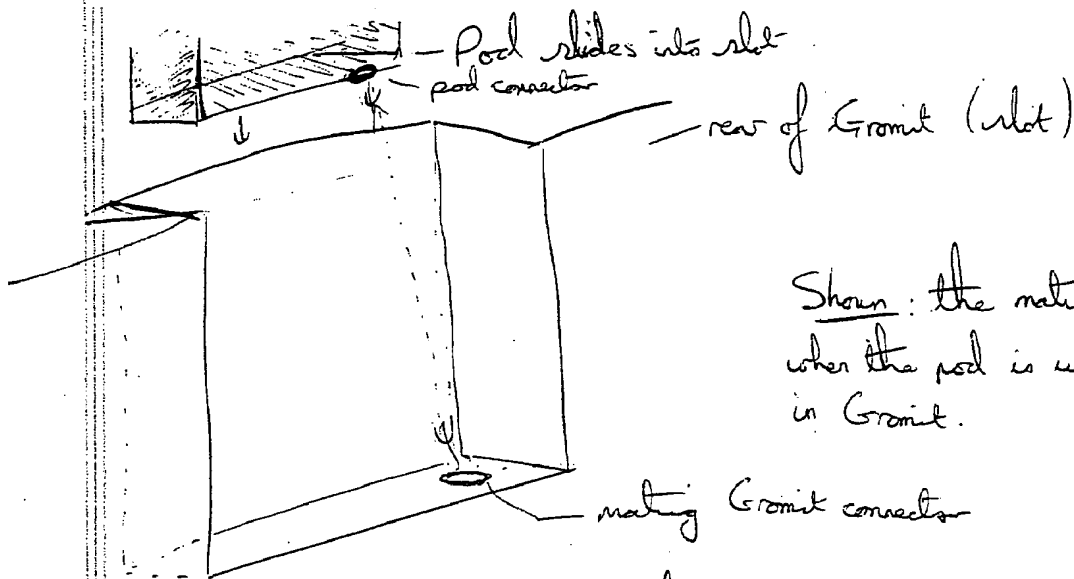


Figure 3A



Shown: the mating connector pairs when the pod is used when docked in Gromit.

usual approach to mating connectors

Connector detail (for example).

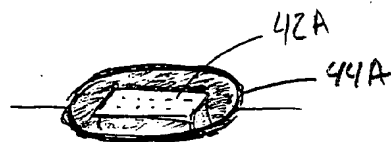
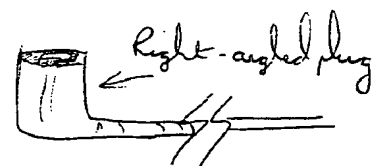
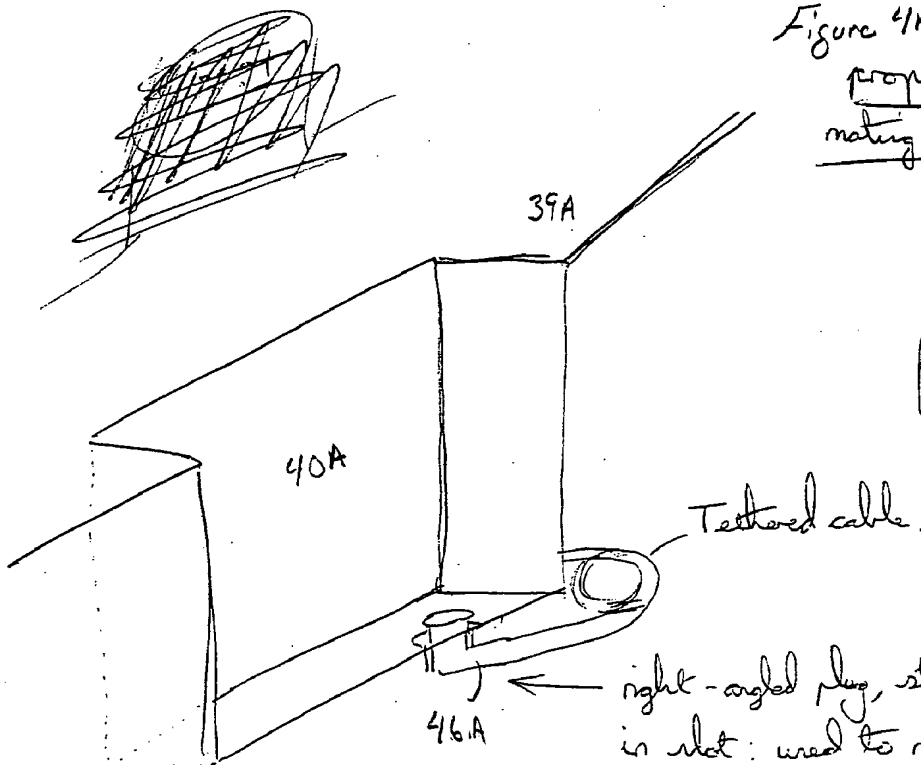
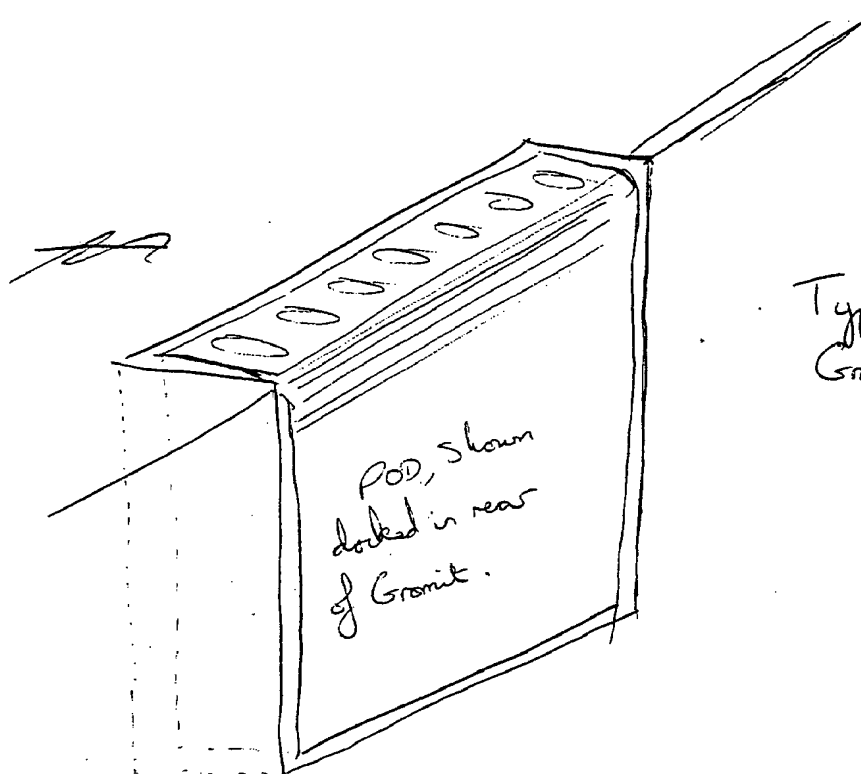


Figure 4A'
proposed approach to mating connectors

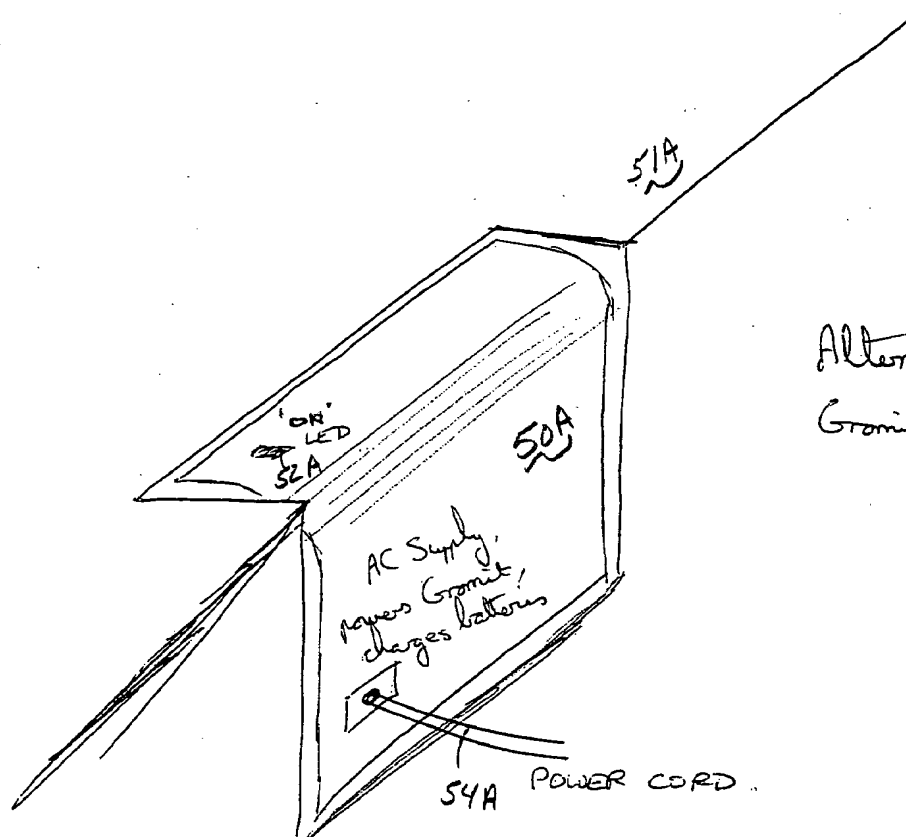


right-angled plug, stowed in cut-out in slot: used to mate w/ pod (as shown) or mates w/ pod when not docked if cable + connector is removed from slot.

Figure 4A

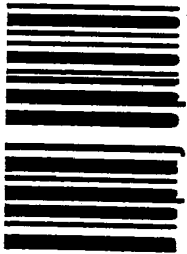


Typical use of Gromit slot.

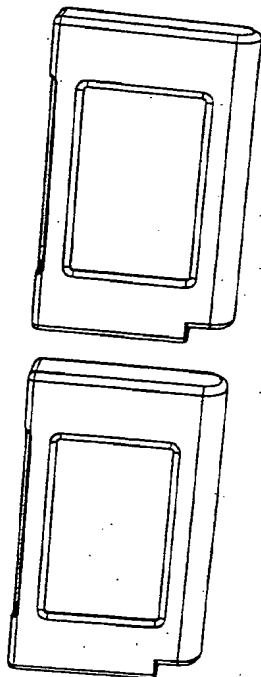


Alternate use of Gromit slot.

Figure 5A

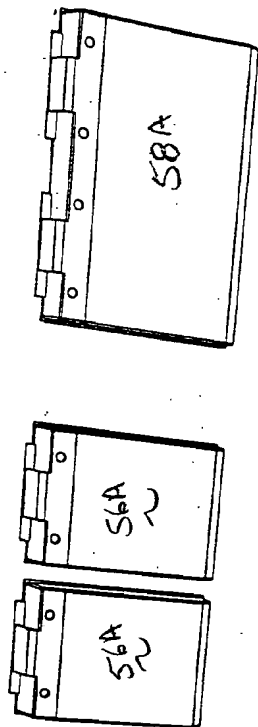


1. LCD for use indoors and outdoors
2. EL for enhanced indoor viewing



Power Options:

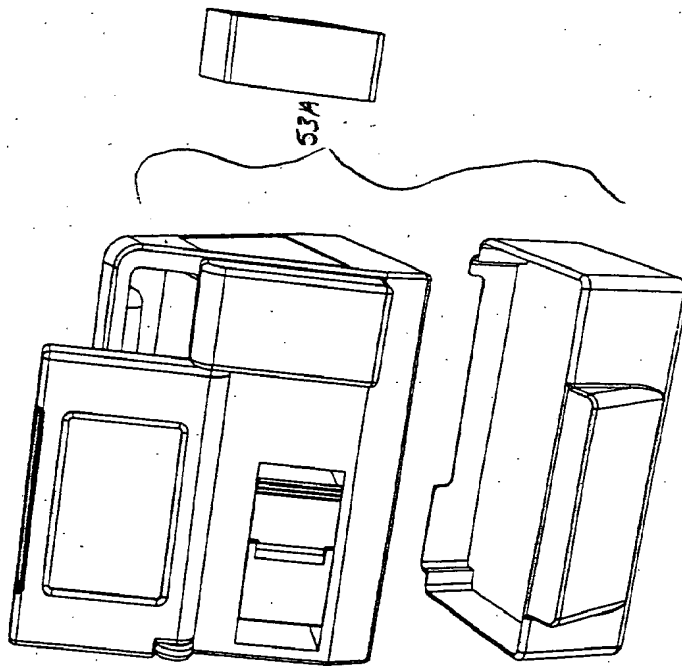
1. Two Fastpak or Fastpak+ NiCd batteries
2. SLA / AC power module
3. SLA in modified Fastpak case



Modularity

Stand-alone monitor with soft controls to accommodate a variety of parameter options.

"Dumb" defibrillator with minimal controls attaches to bottom of monitor. Defibrillator obtains power from monitor.



Monitoring Options:

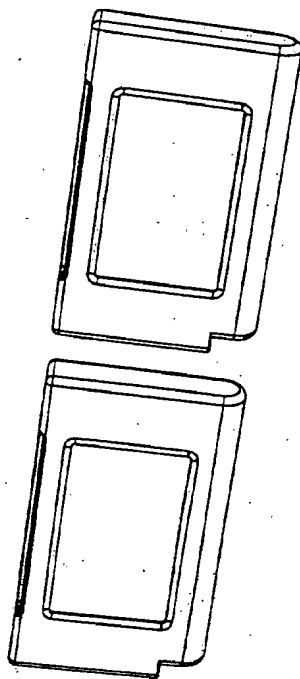
A single slot is provided in the monitor to allow for different parameters to be monitored. Modules will be configured with 2 or 3 combinations of parameters to accommodate a range of users.

Figure 5A'

Family Code Team

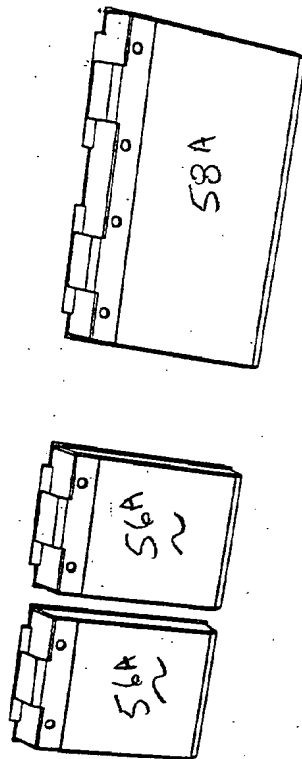
Display Options:

1. LCD as a lower-priced option
2. EL for enhanced indoor viewing

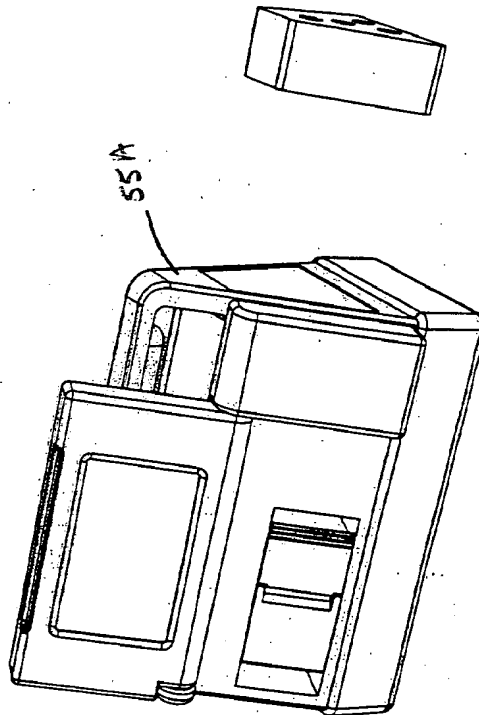


Power Options:

1. Two Fastpak or Fastpak+ NiCd batteries
2. SLA / AC power module
3. SLA in modified Fastpak case



Integrated Monitor/Defibrillator/Pacer



Monitoring Options:

A single slot is provided in the monitor to allow for different parameters to be monitored. Modules will be configured with 2 or 3 combinations of parameters to accommodate a range of users.

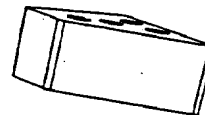


Figure 5A"

ZEBRA AL F... CONCEPT

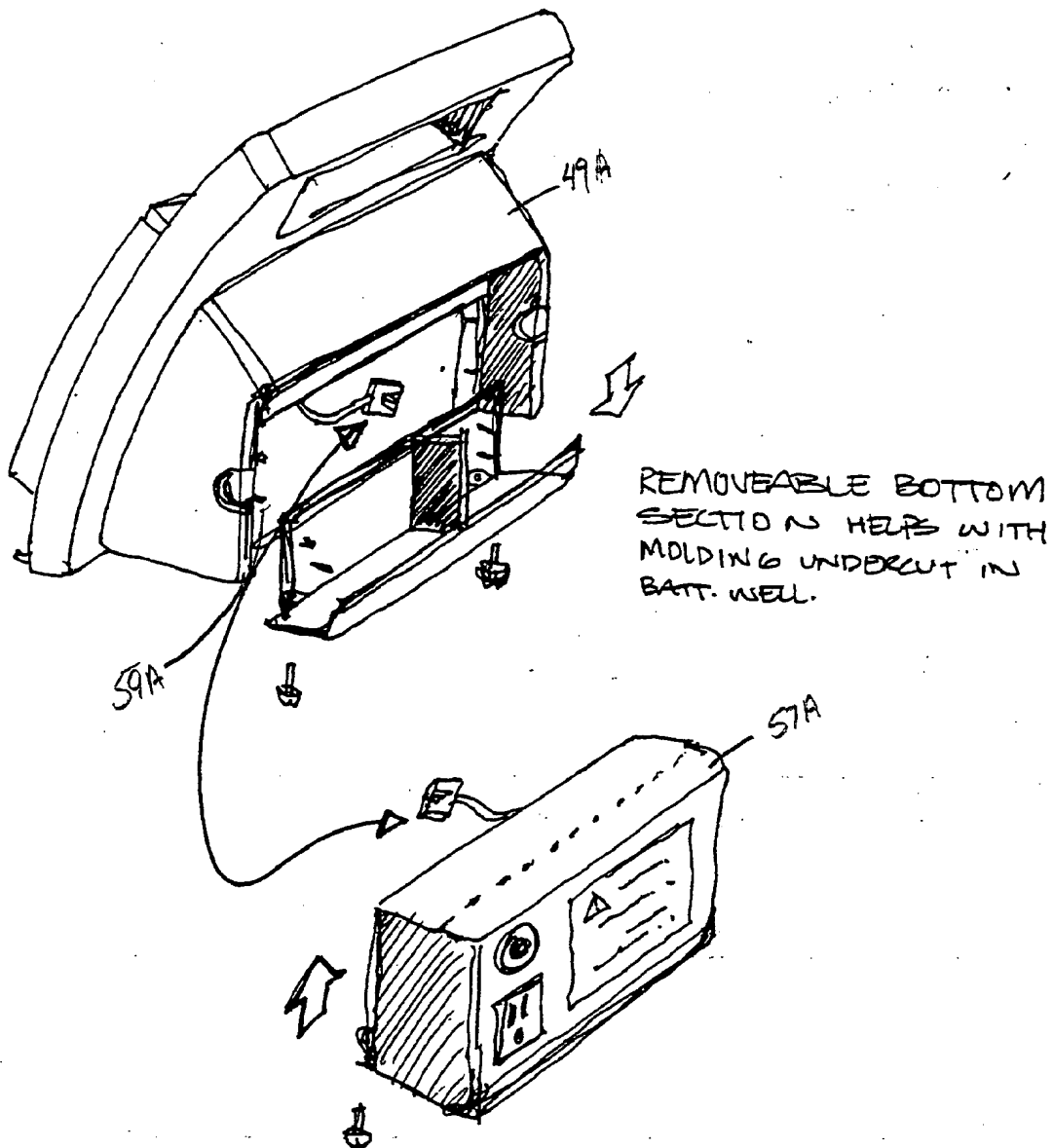
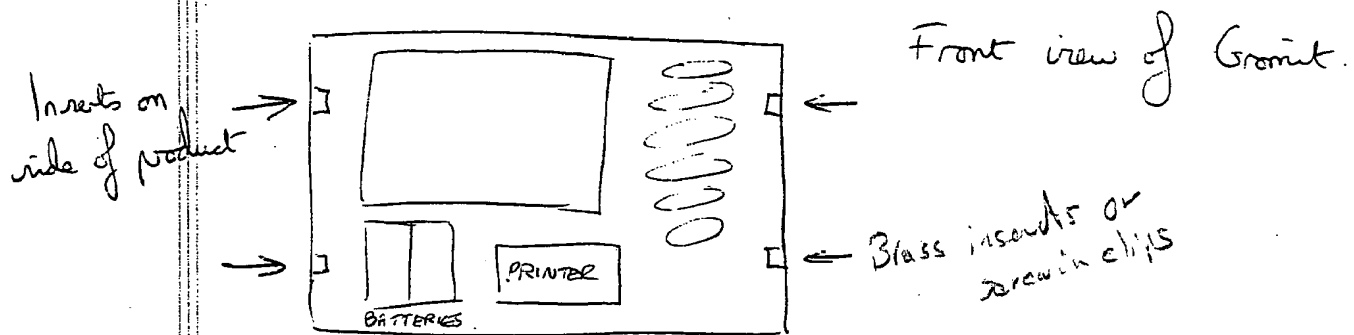


Figure 5A'''



Inserts can be used for a) clips to attach hard paddles:

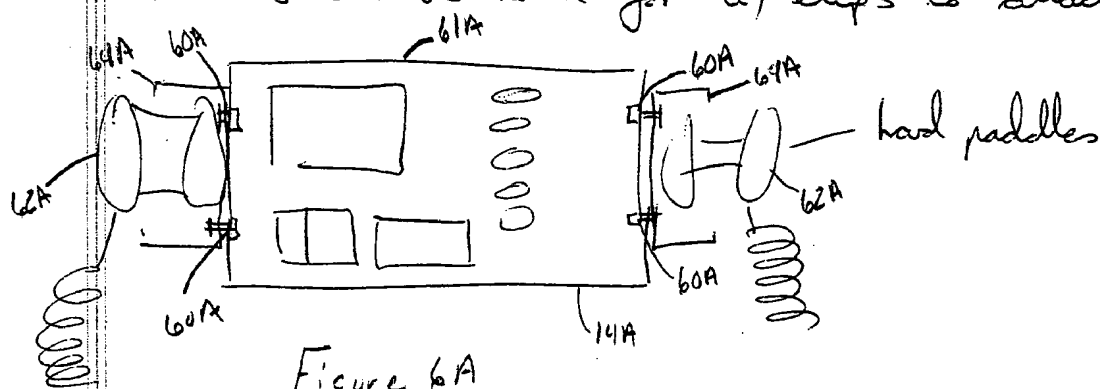
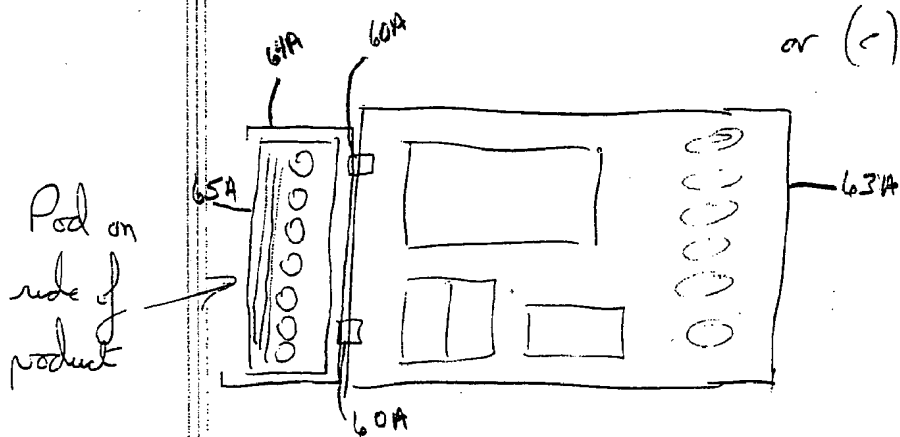


Figure 6A

or (b) side-mounted carry bags
or (c) side-mounted pod



advantages: easily visible connectors for tableshorting
easier access for connection/disconnection

Figure 6A'

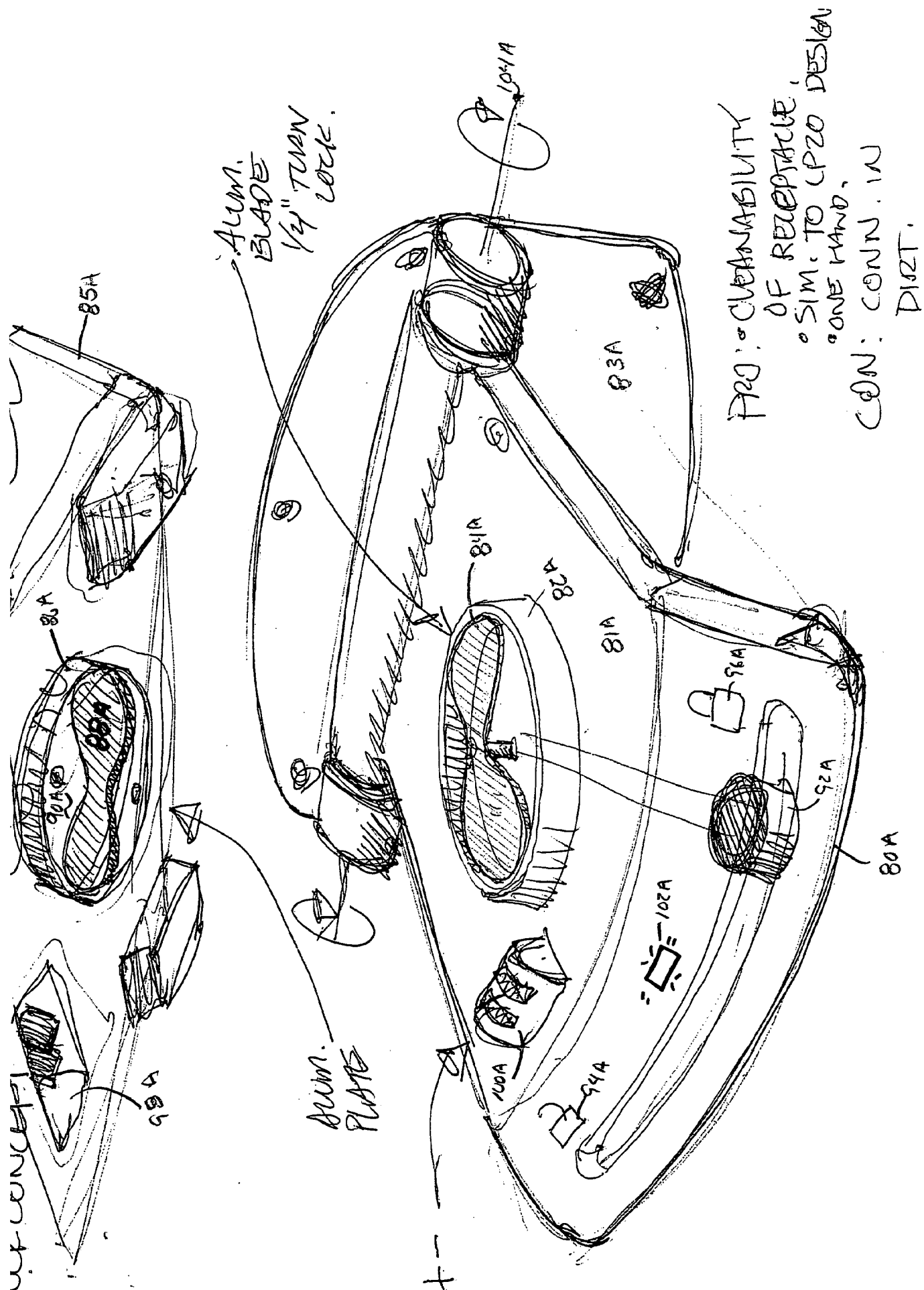


Figure 8A

Wallace Docking Station Brainstorm Session

Name: _____

Extension: _____

The Wallace Docking Station performs two main roles. It restrains Gromet under semi-violent maneuvers (25G's) and provides DC power to charge batteries and operate the unit. The Docking Station has to work with the bag attached so we are focusing on the bottom area to restrain Gromet and provide 2 electrical contacts. Sketch your ideas below so we may capture them fully.

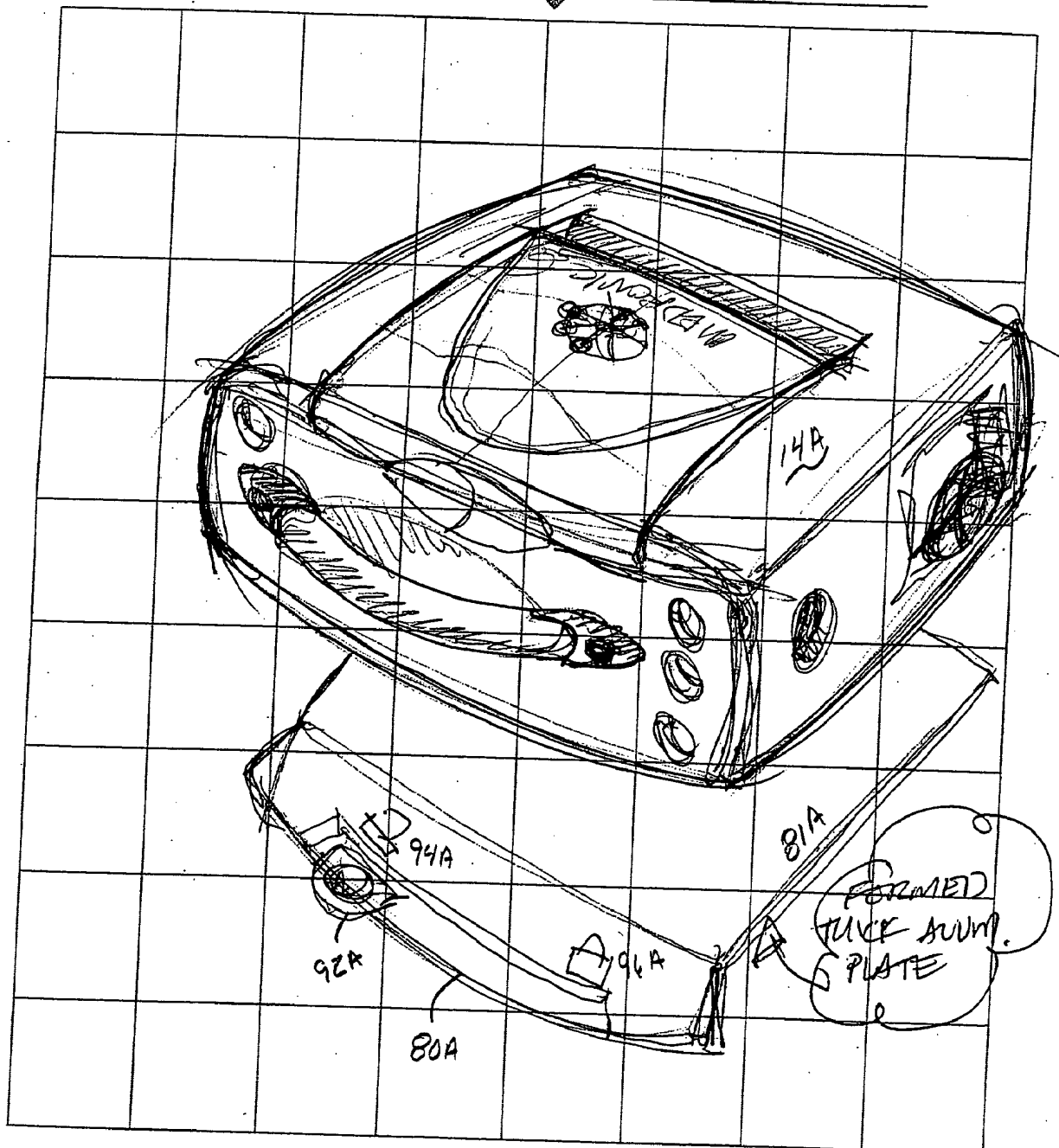


Figure 8A'

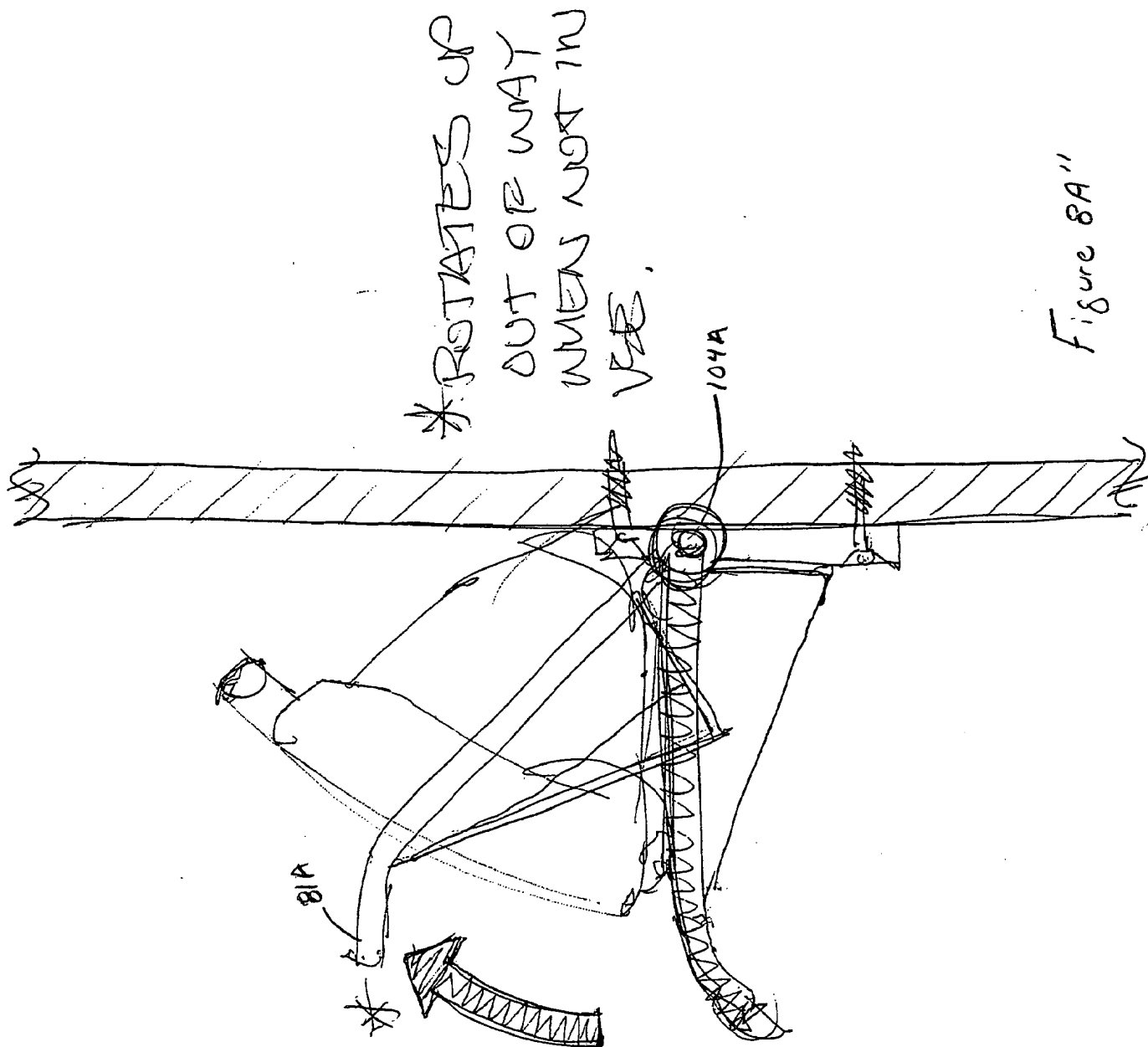


Figure 8A''

Cc9

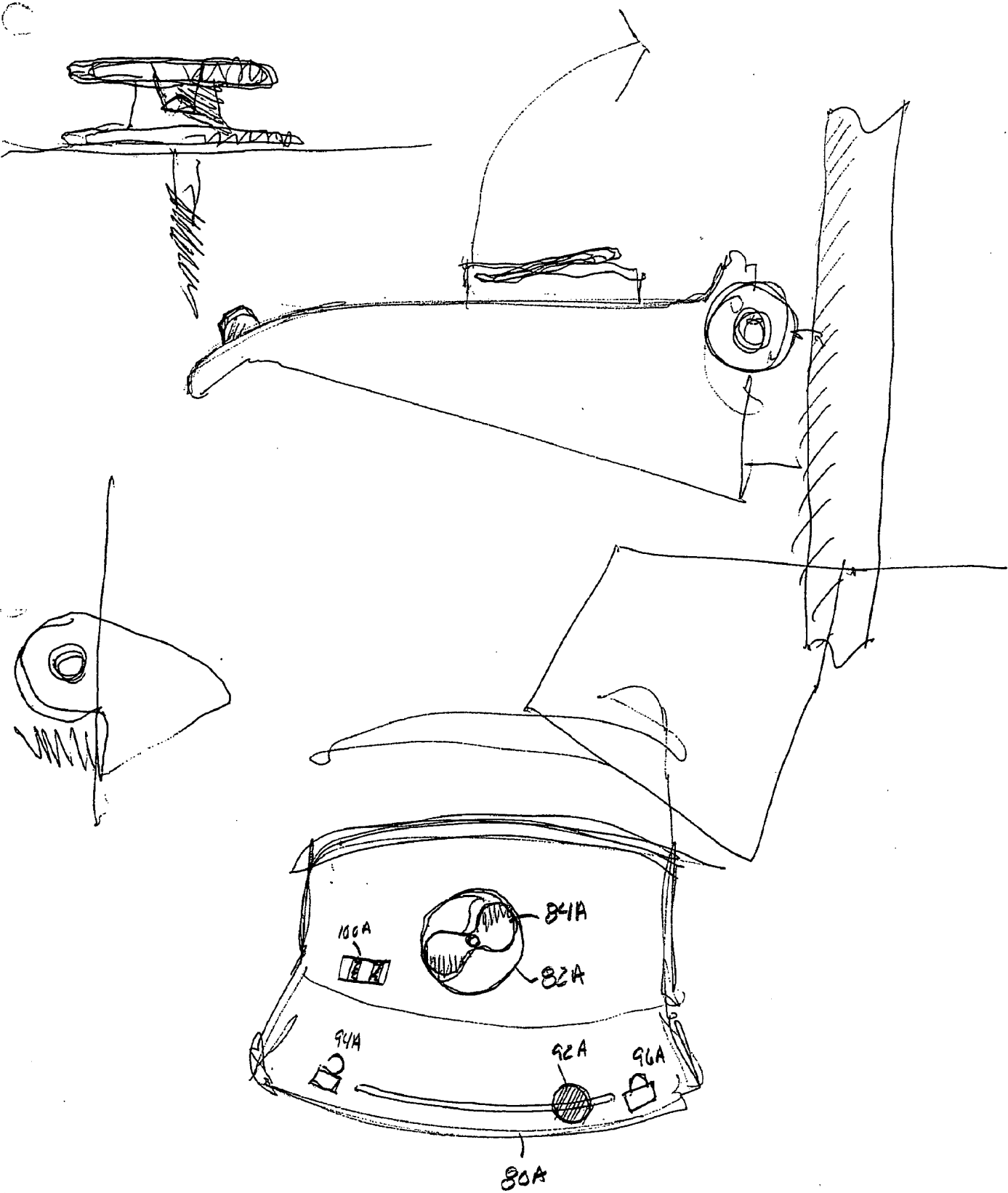


Figure 8A'''

#1

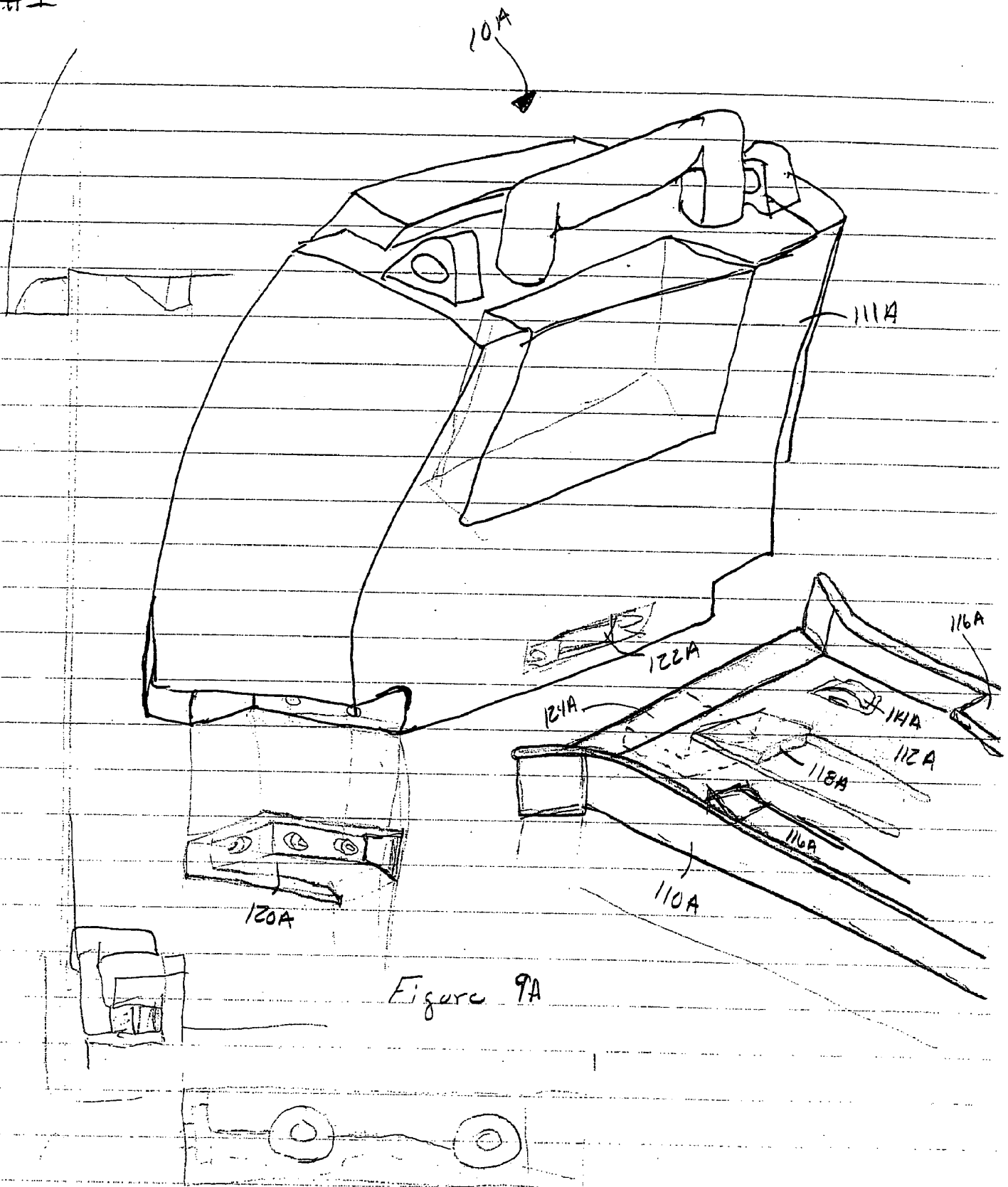


Figure 9A

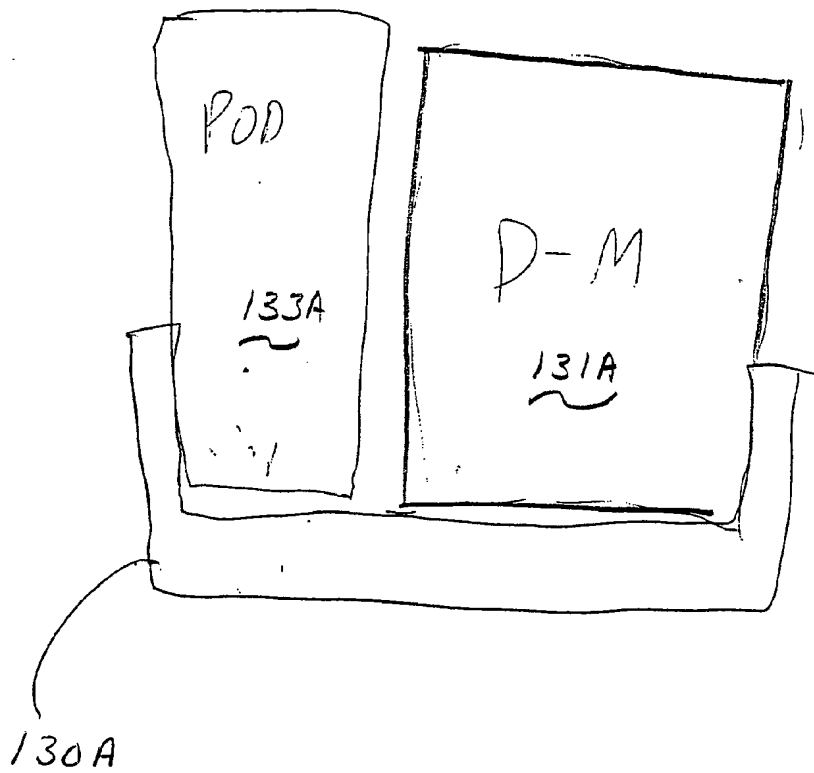


Figure 10A

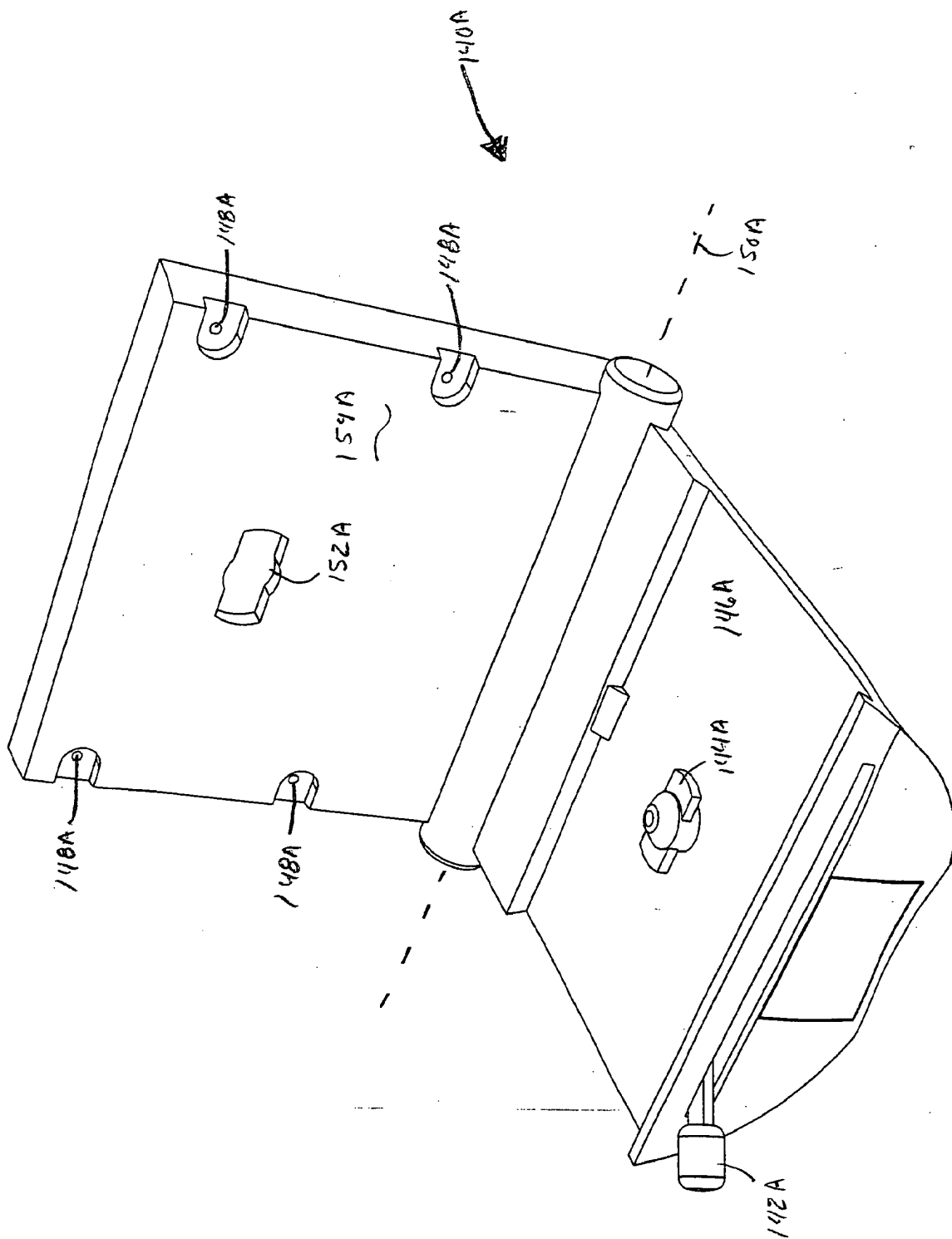


Figure 11A

Dock

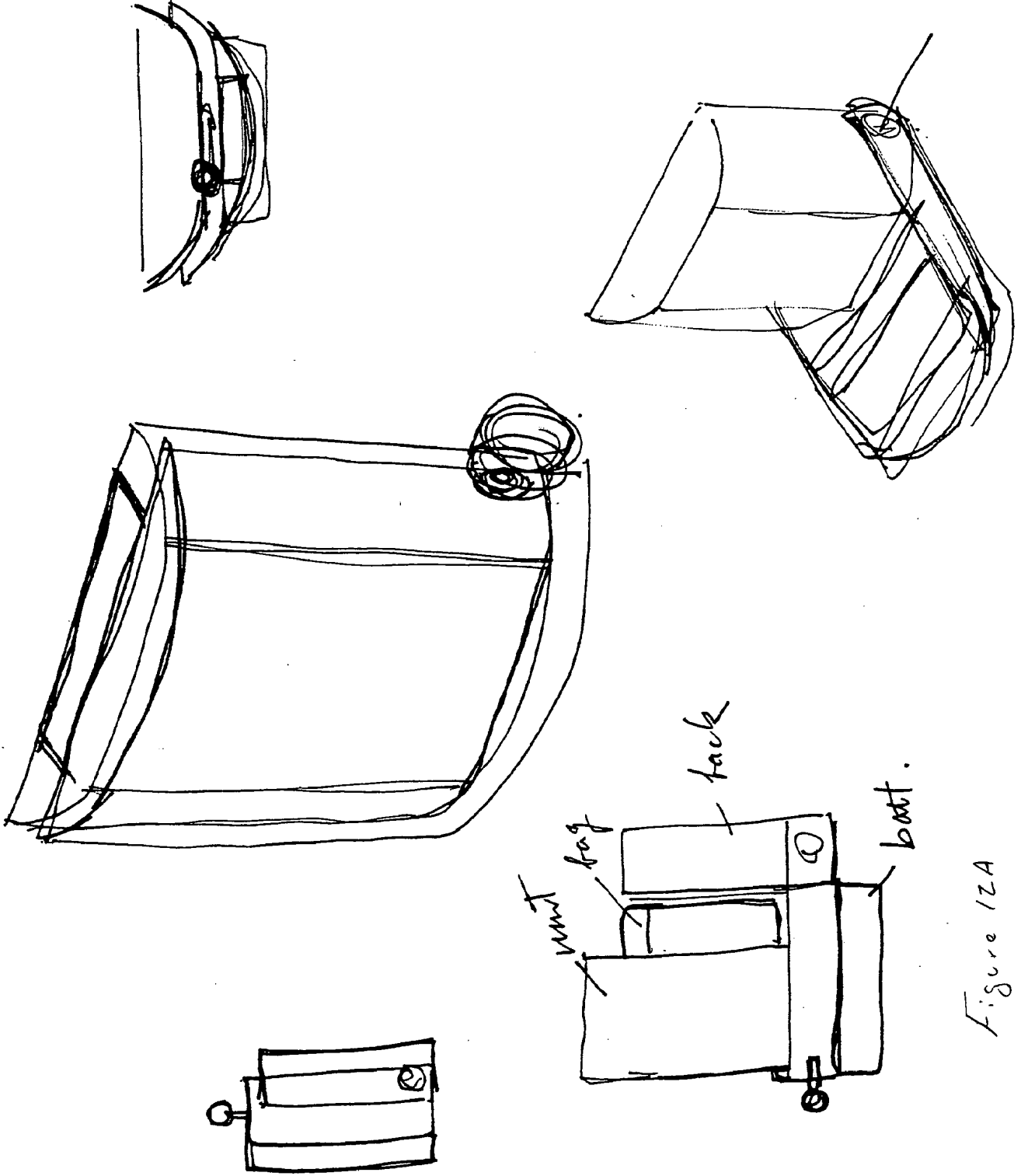


Figure 12A

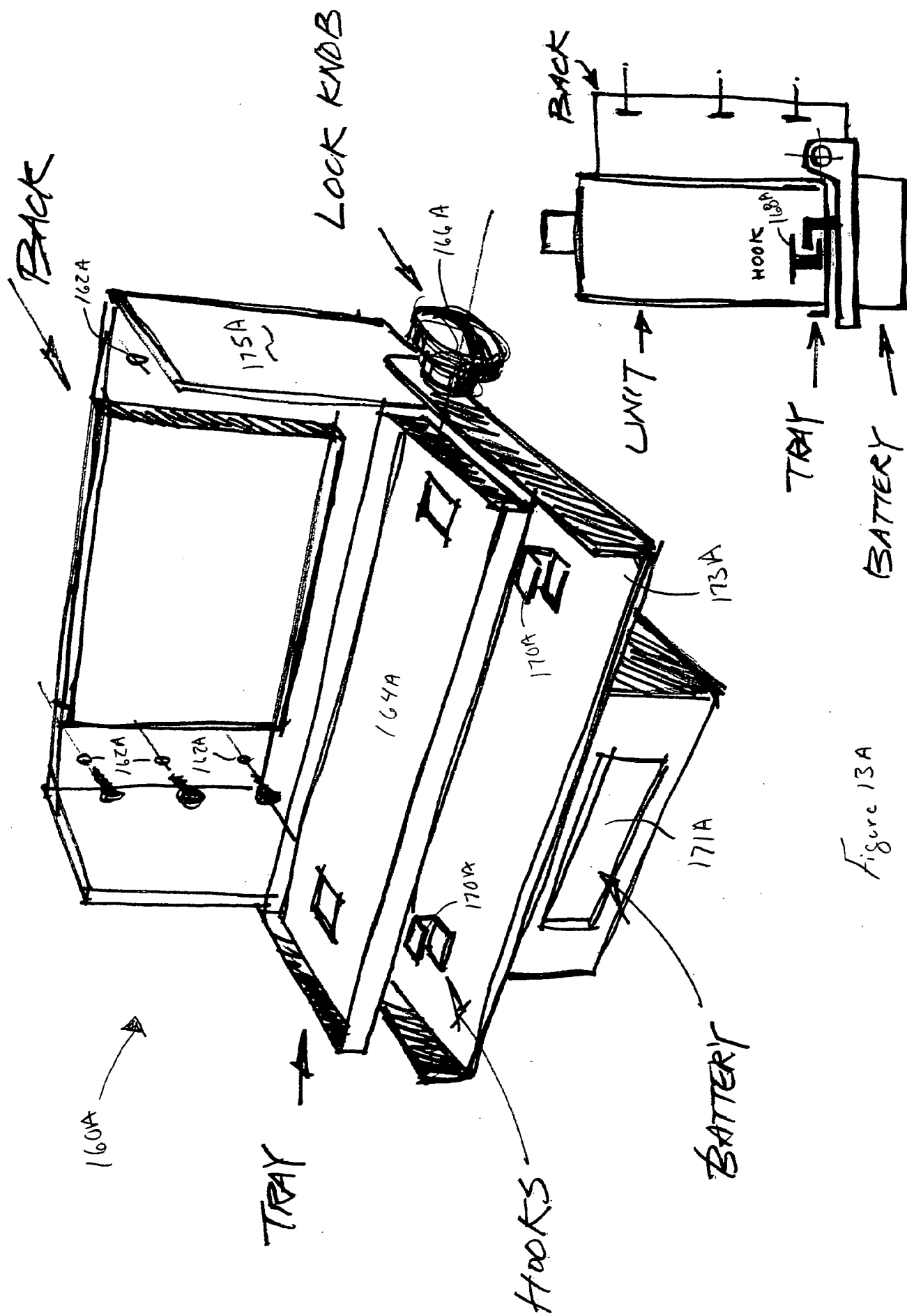
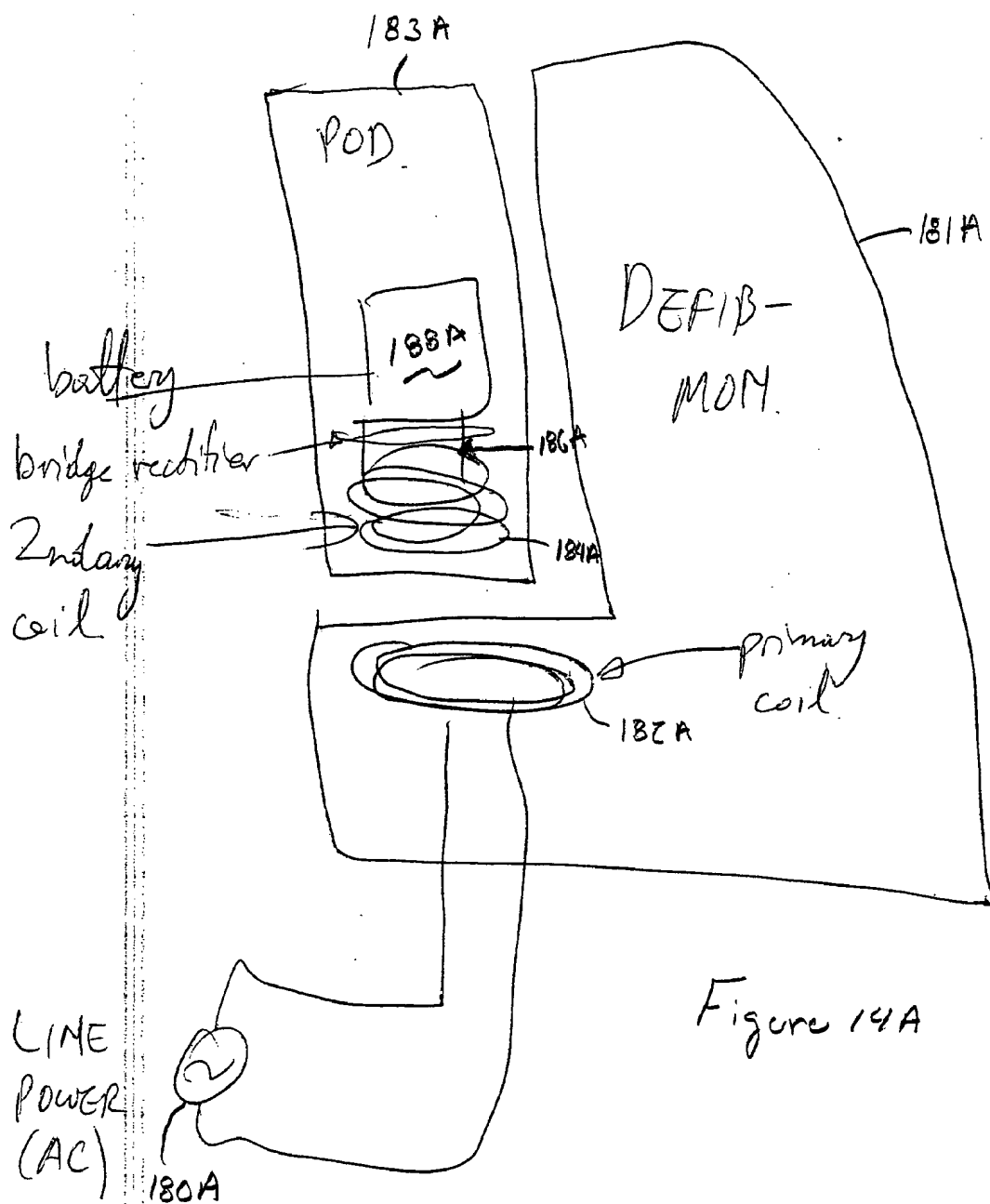


Figure 13A



also its
equivalent: capacitive charging.

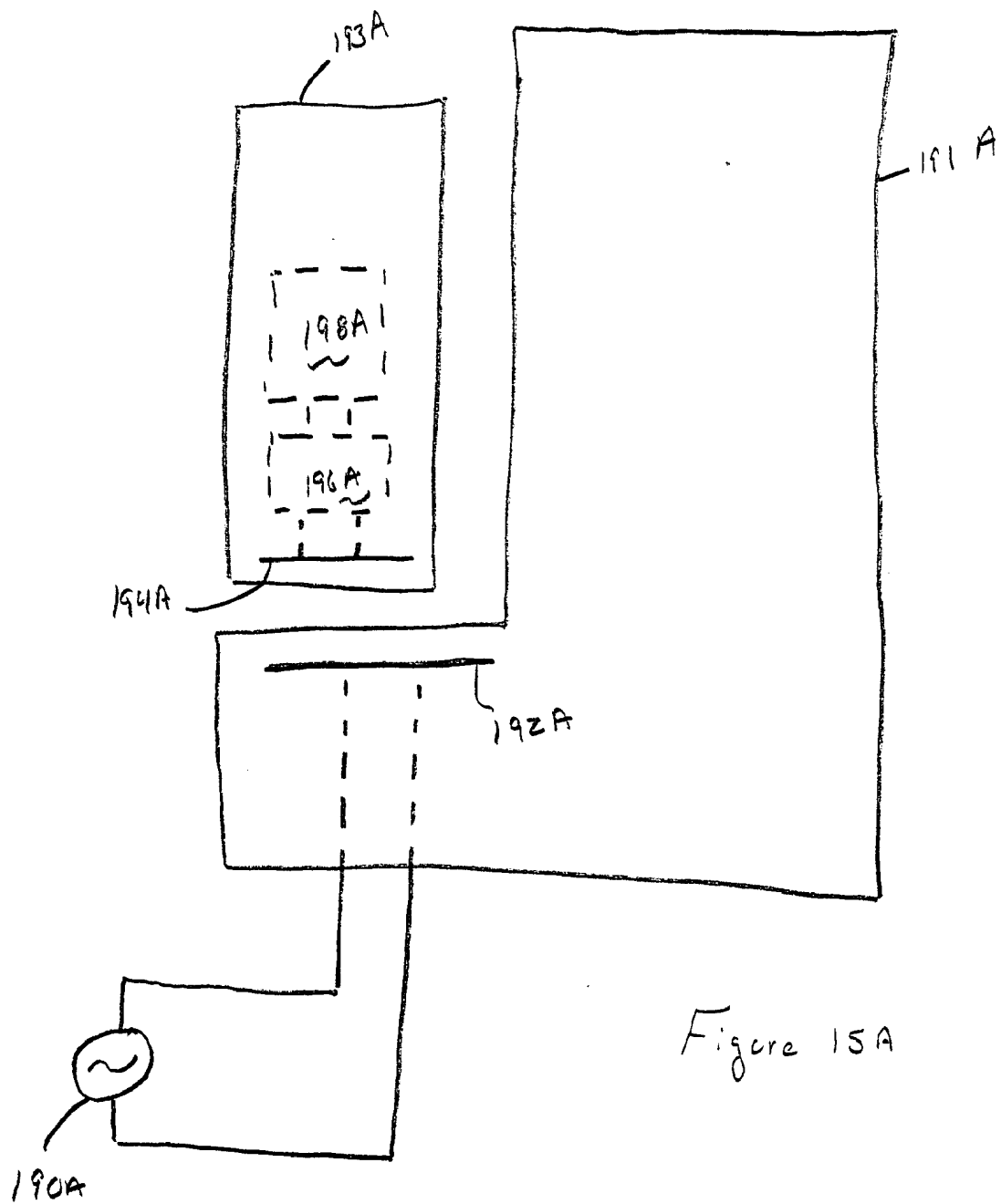


Figure 15A

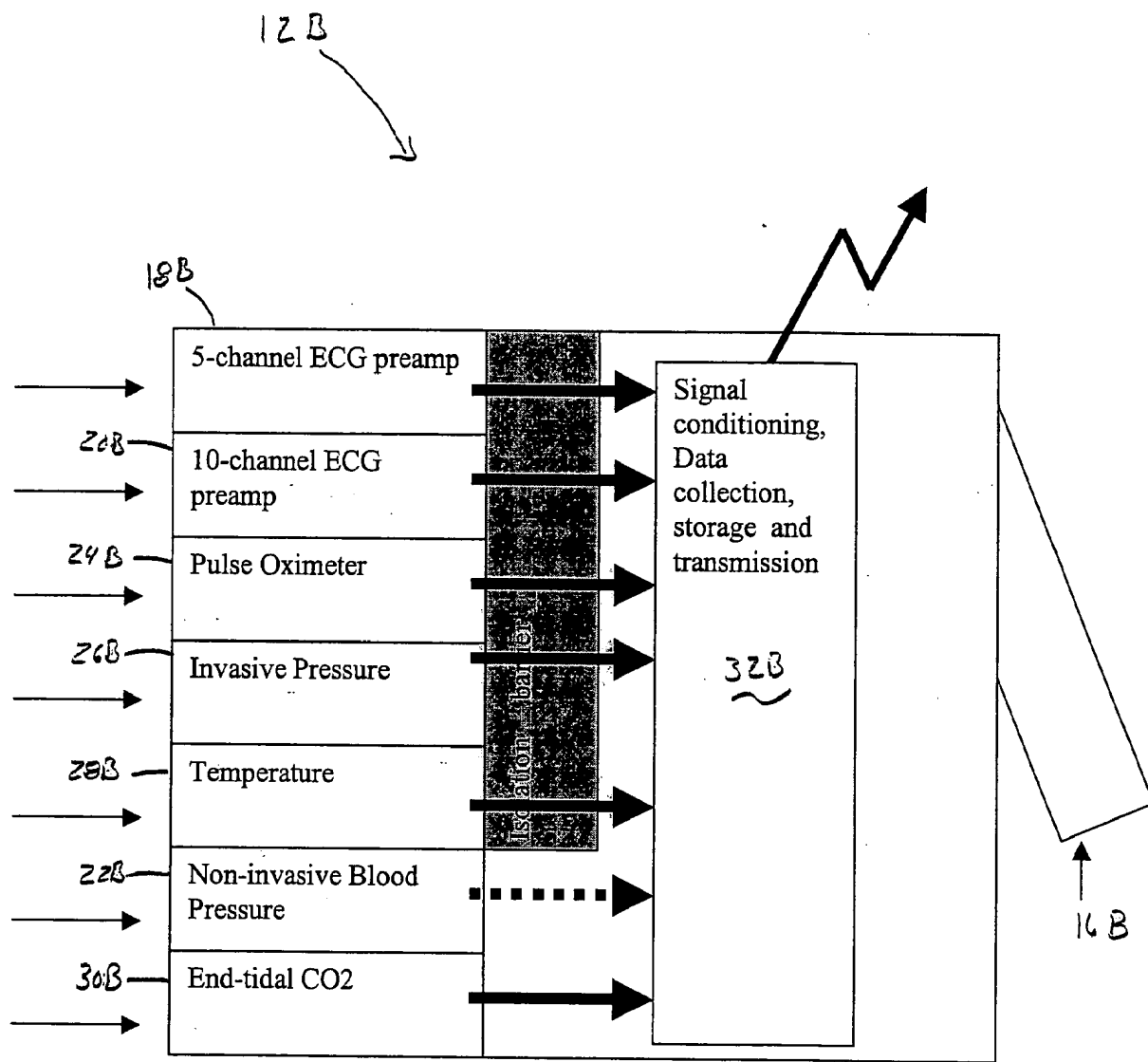


Figure 1B

14B

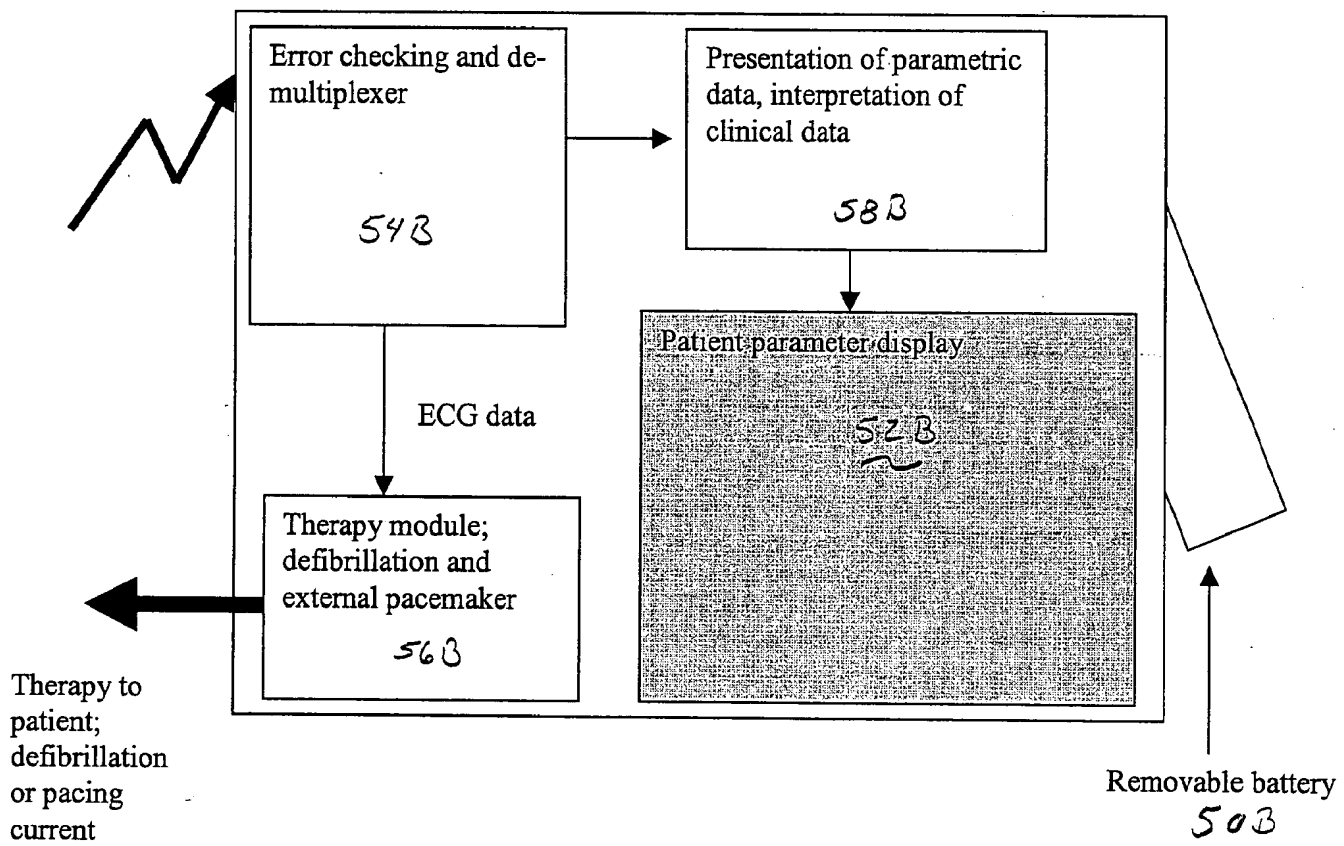


Figure 23

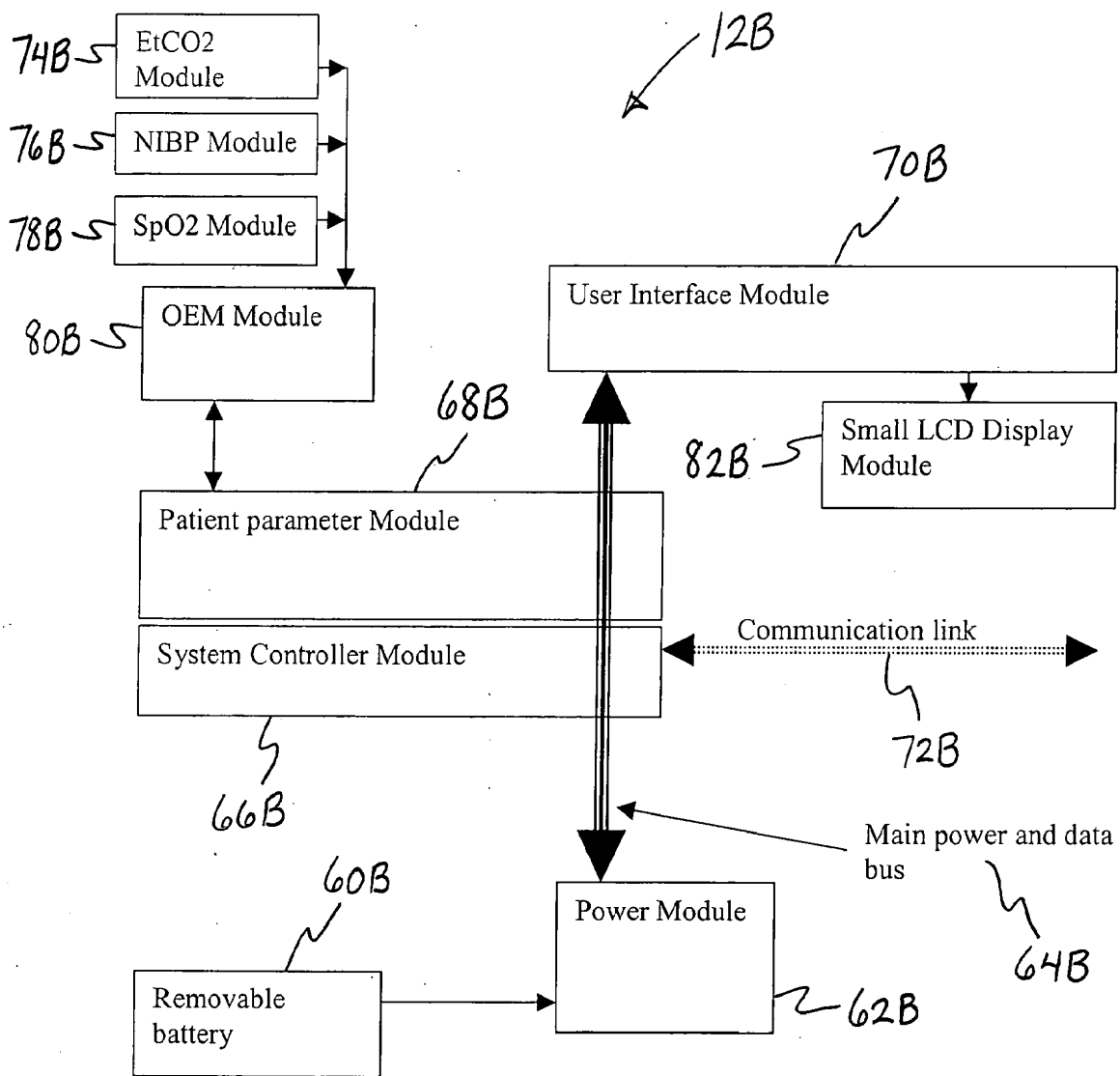


FIGURE 3B

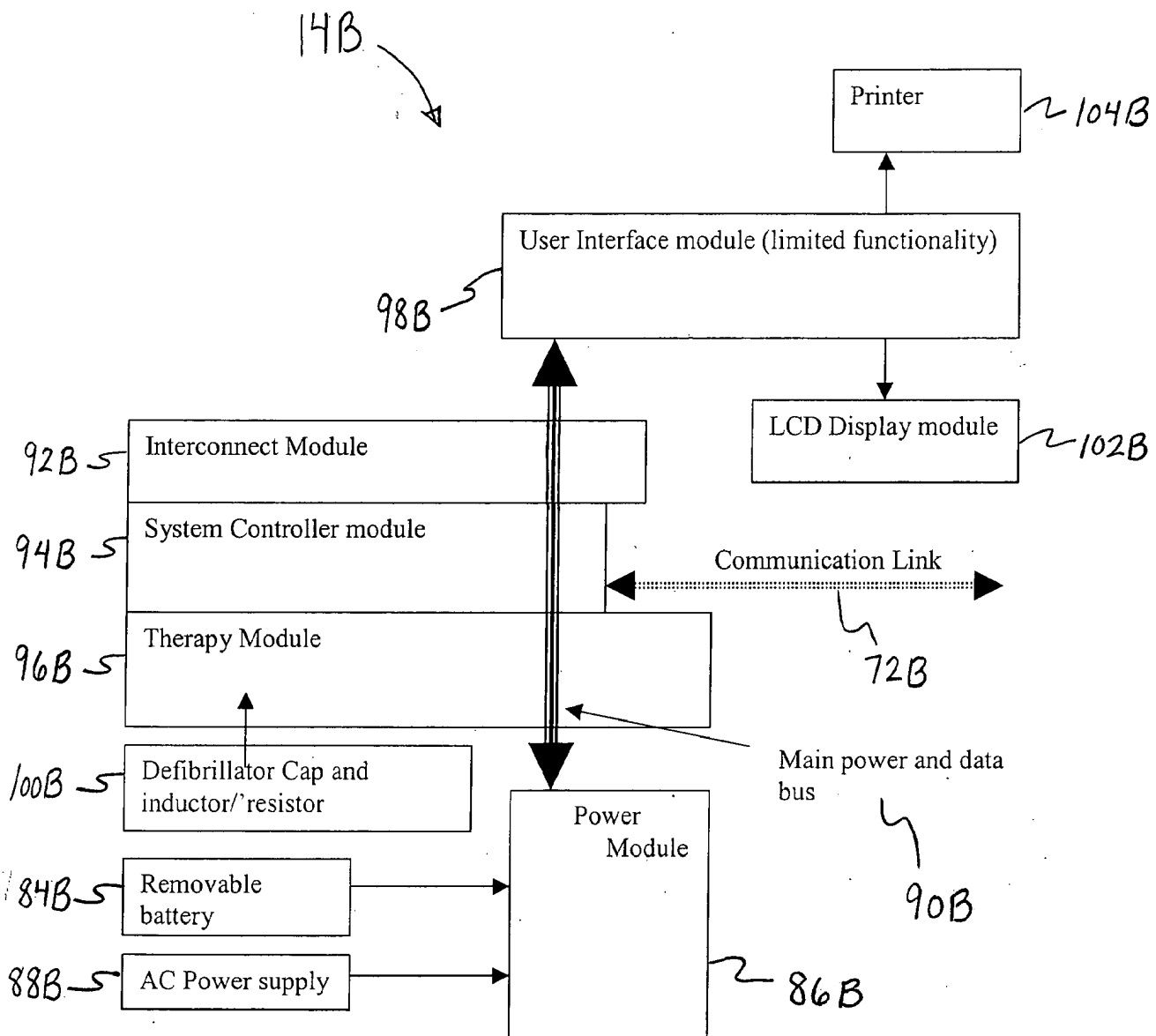


FIGURE 4B

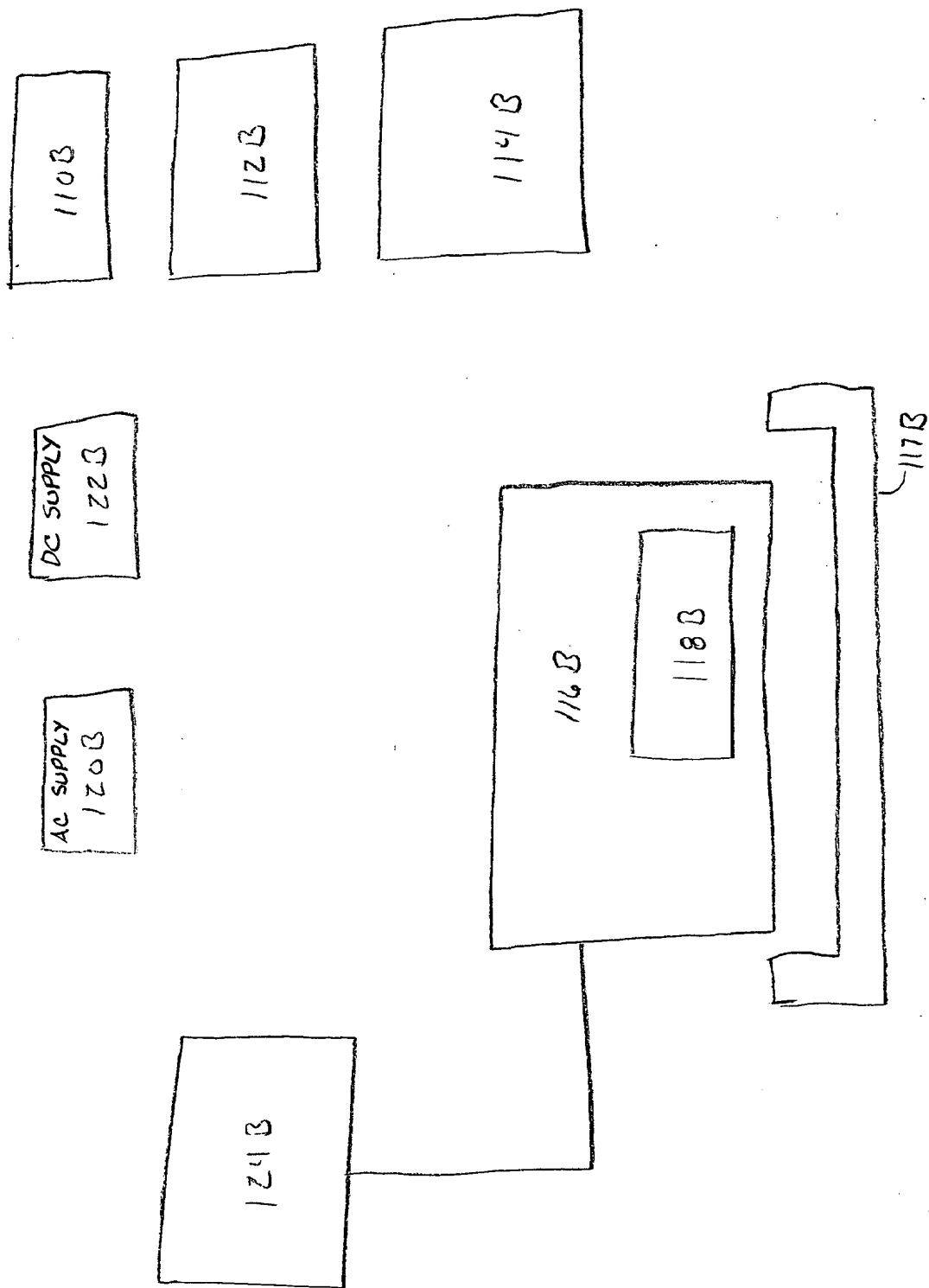


Figure 5B

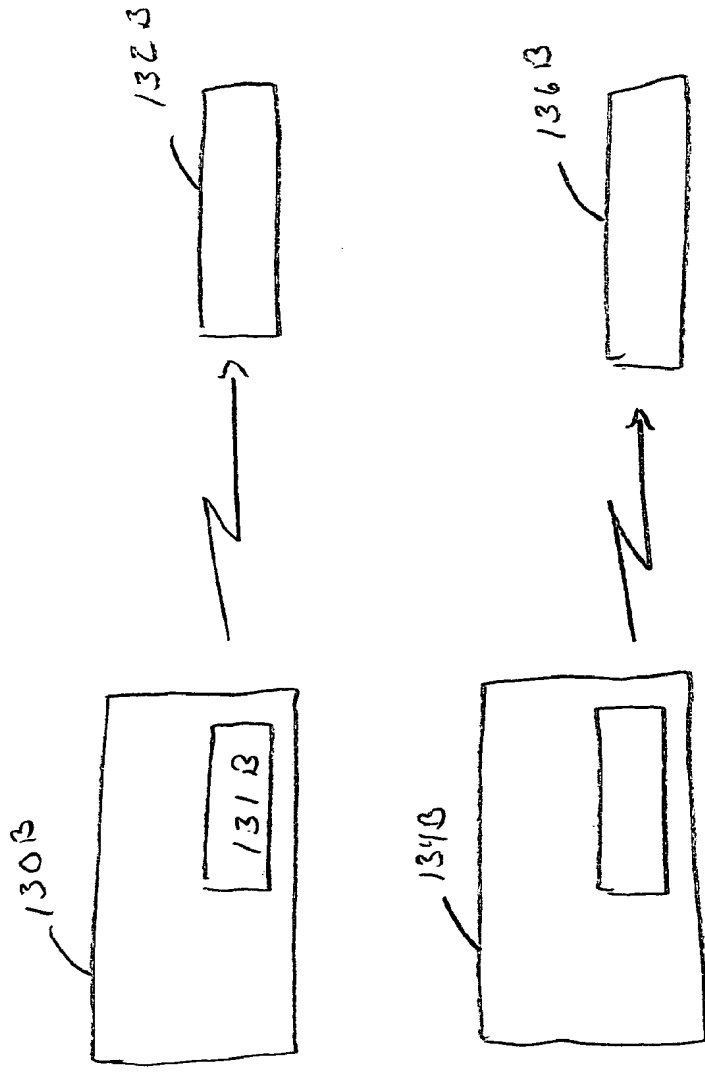


Figure 6B

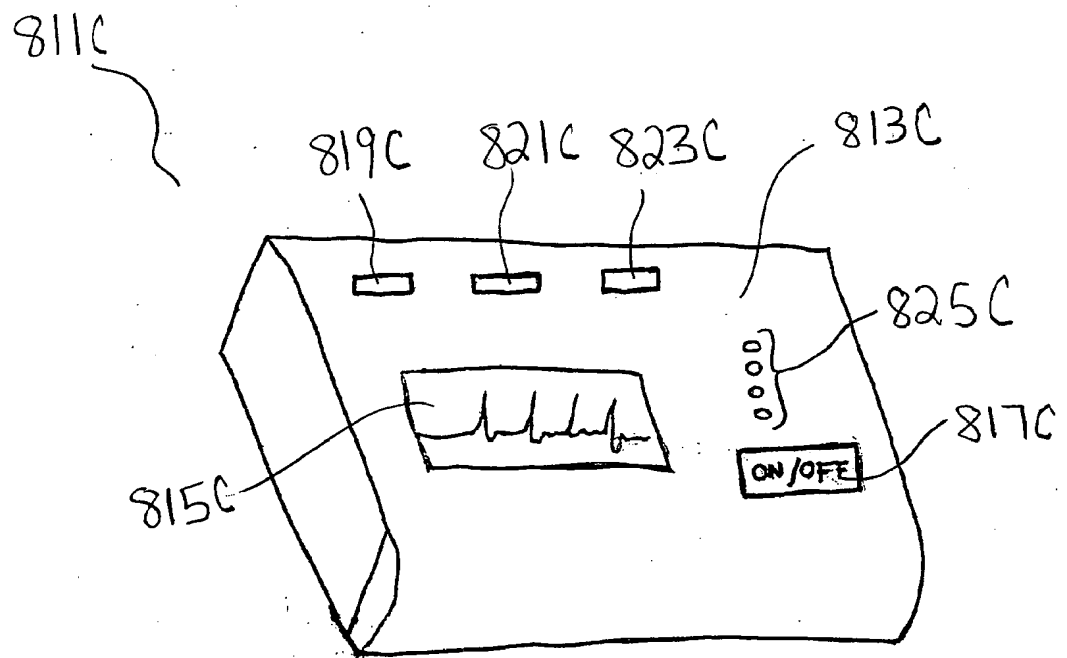


Figure 1C

827C

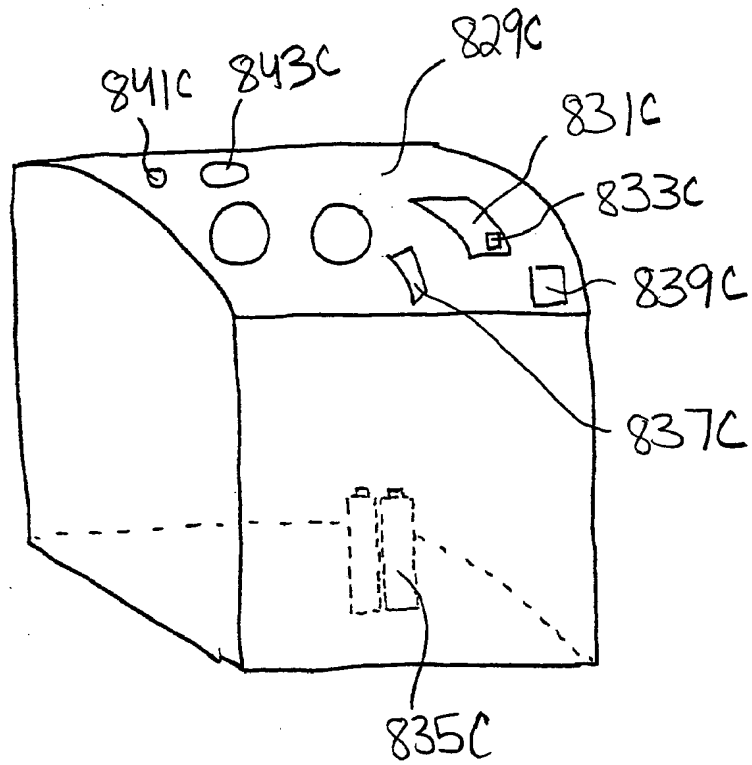


Figure 2C

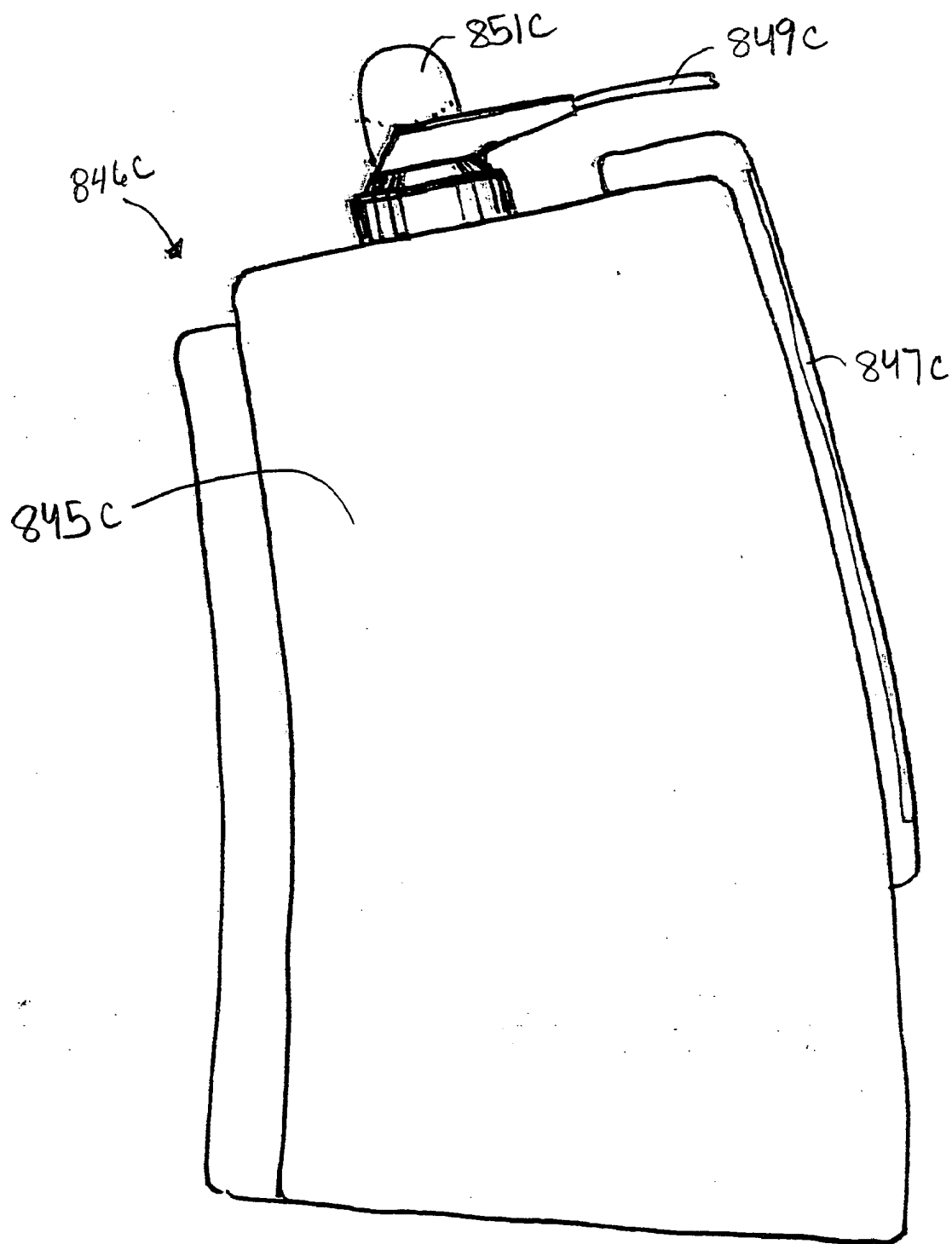


Figure 3c

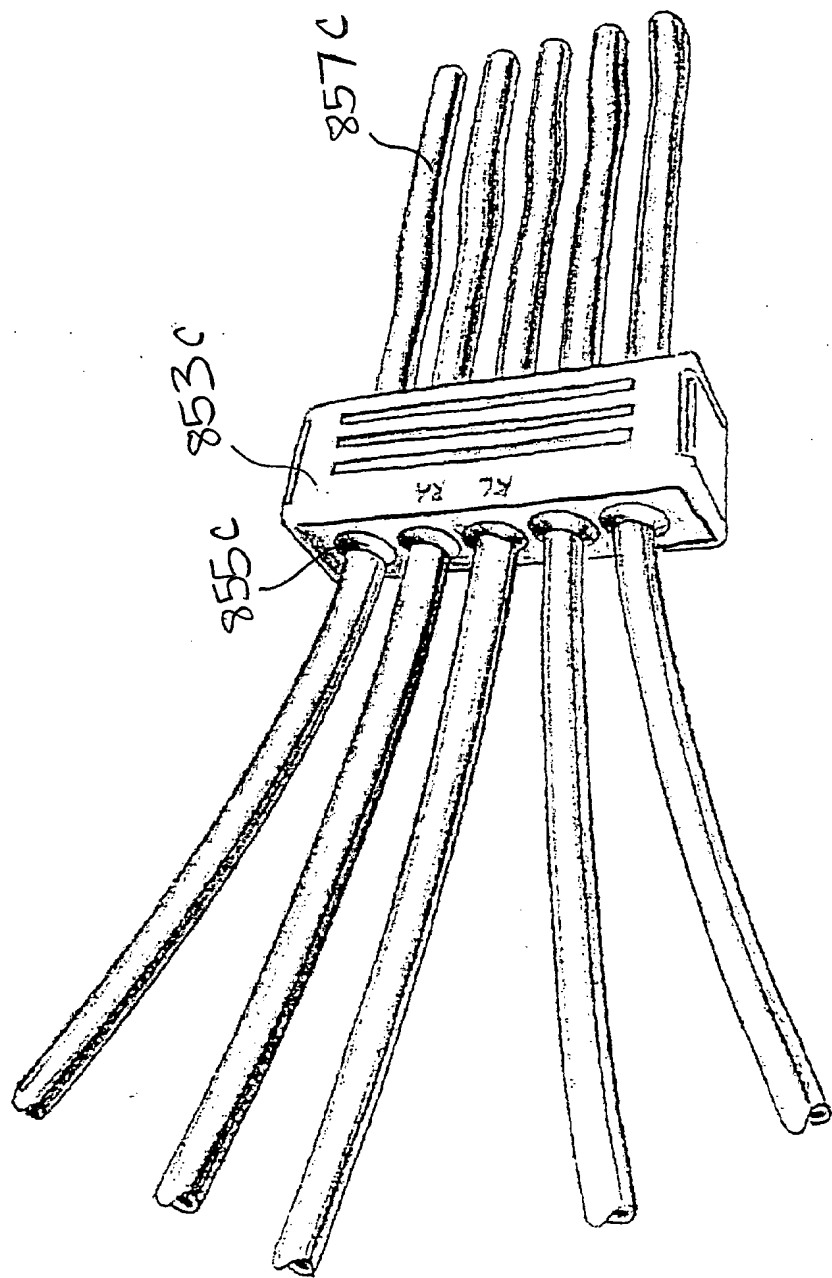


Figure 4c

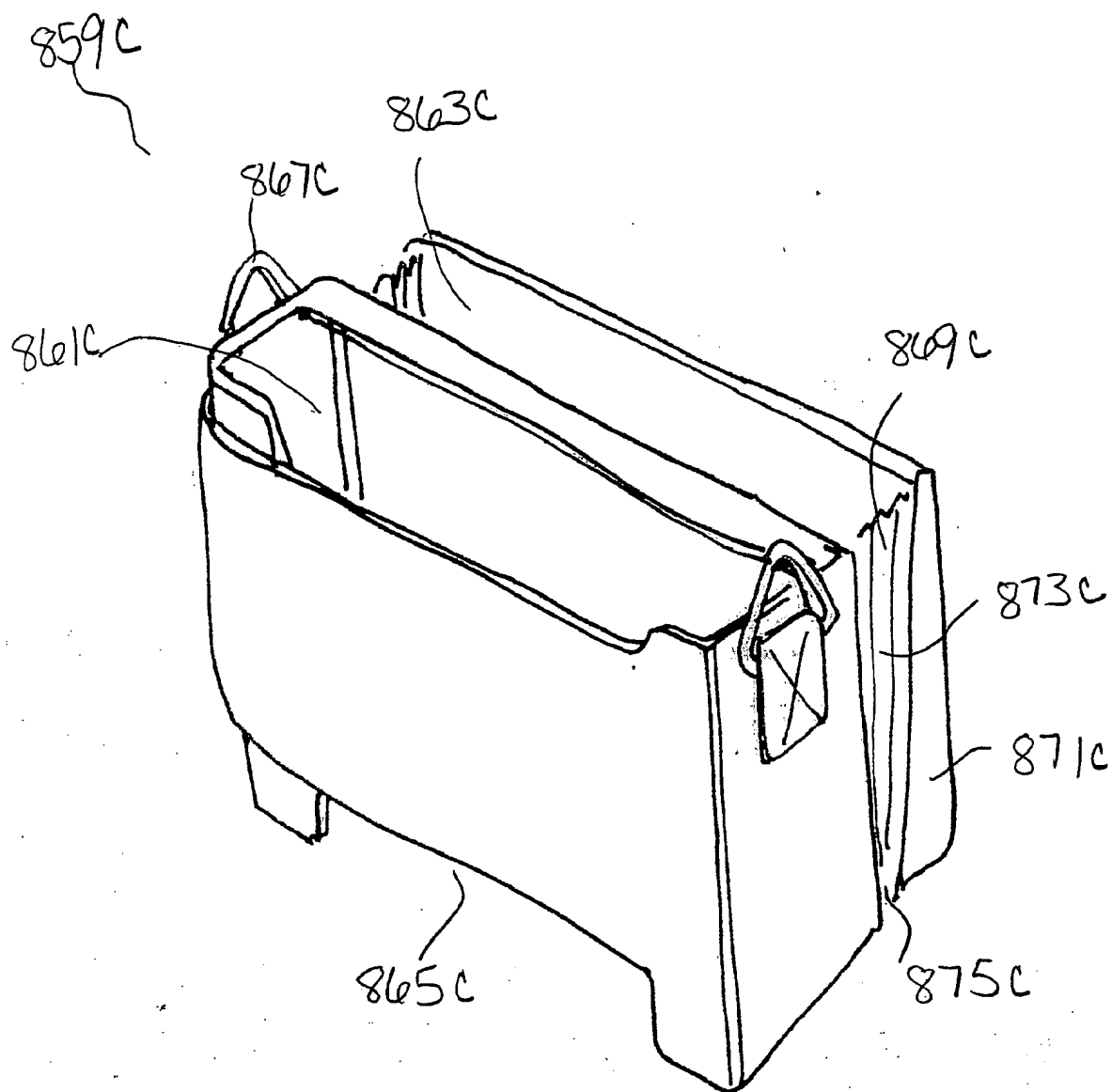


Figure 5C

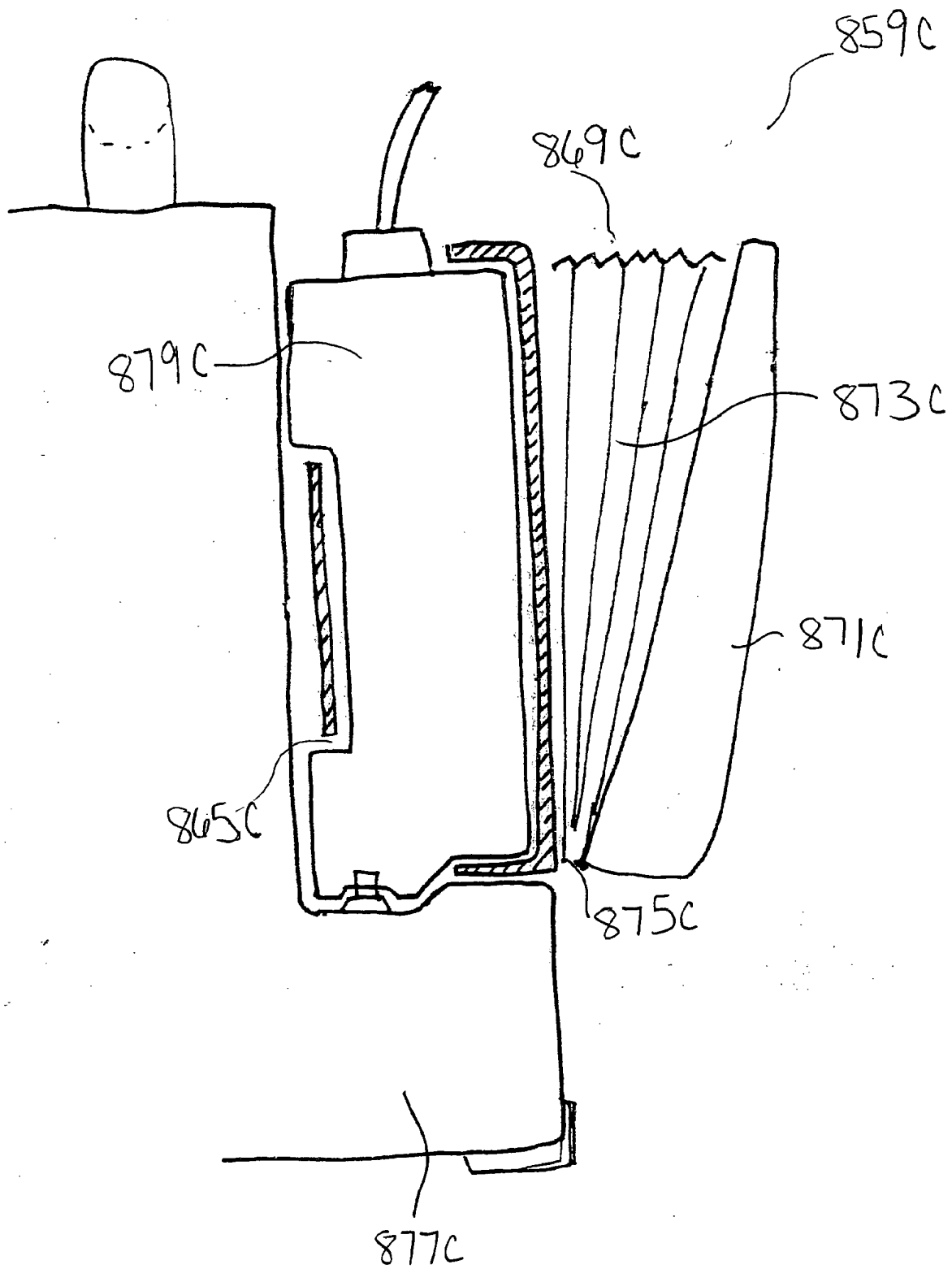


Figure 6C

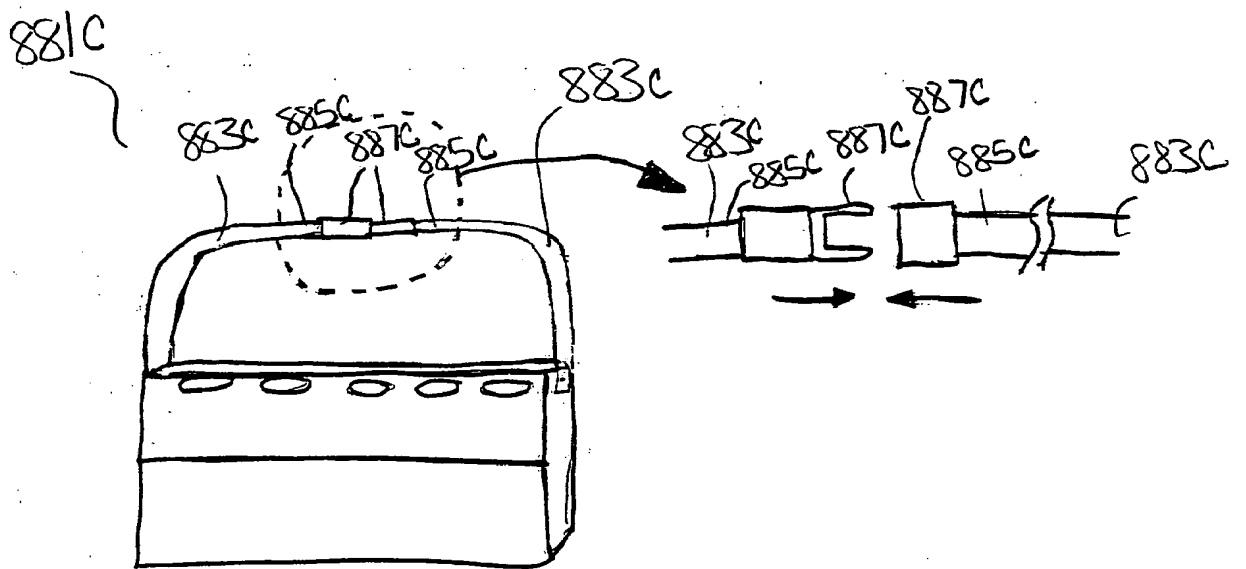


Figure 7c

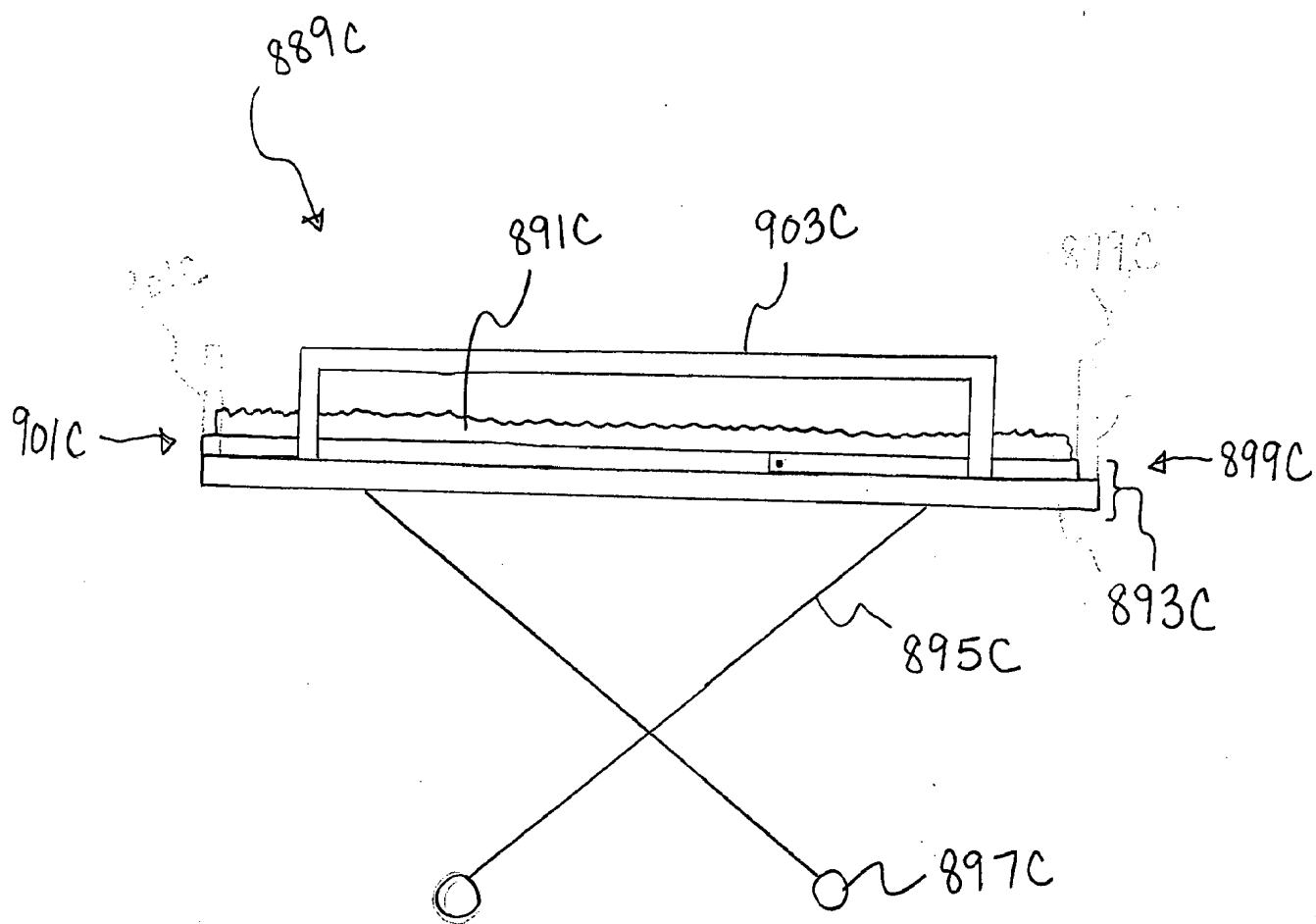


FIGURE 8C

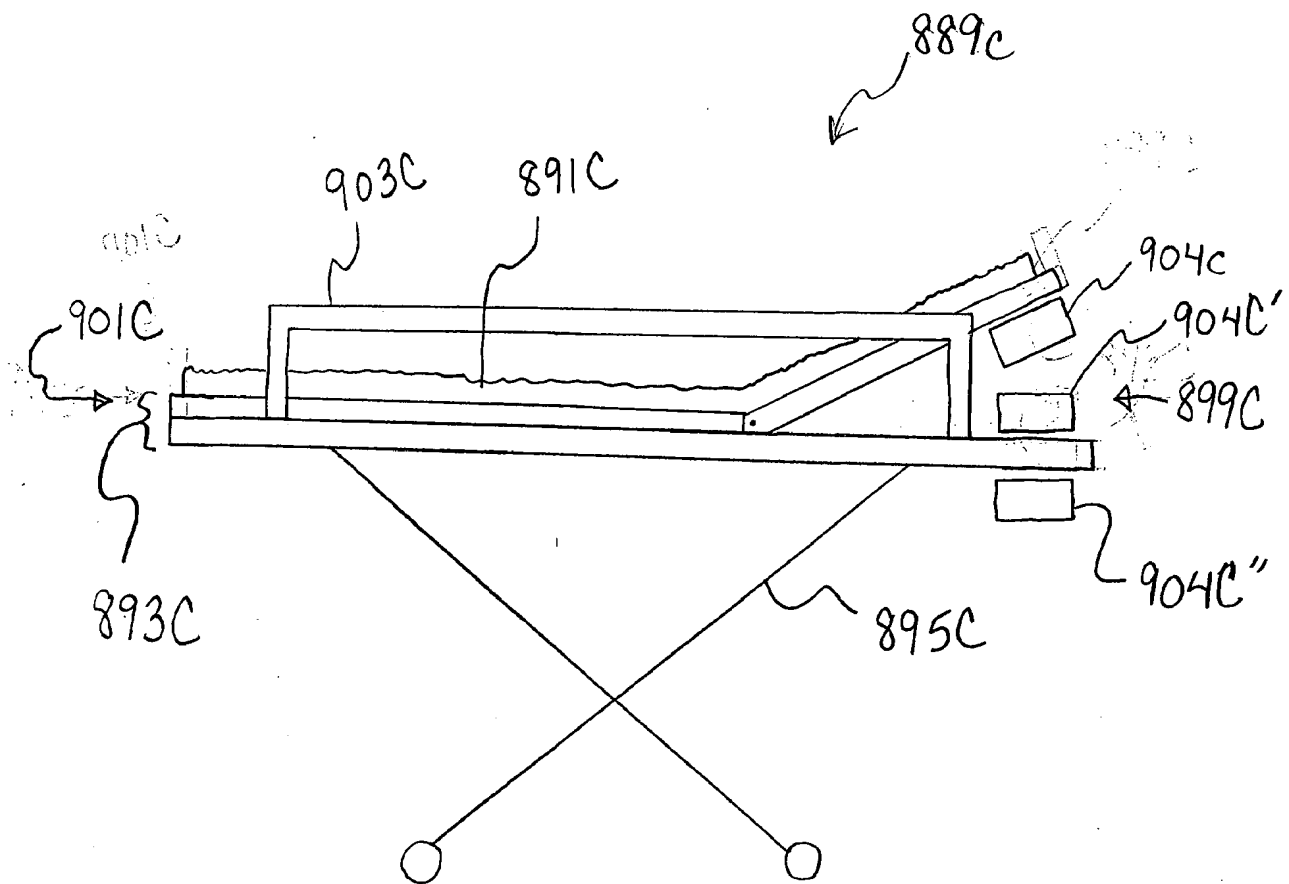


FIGURE 9C

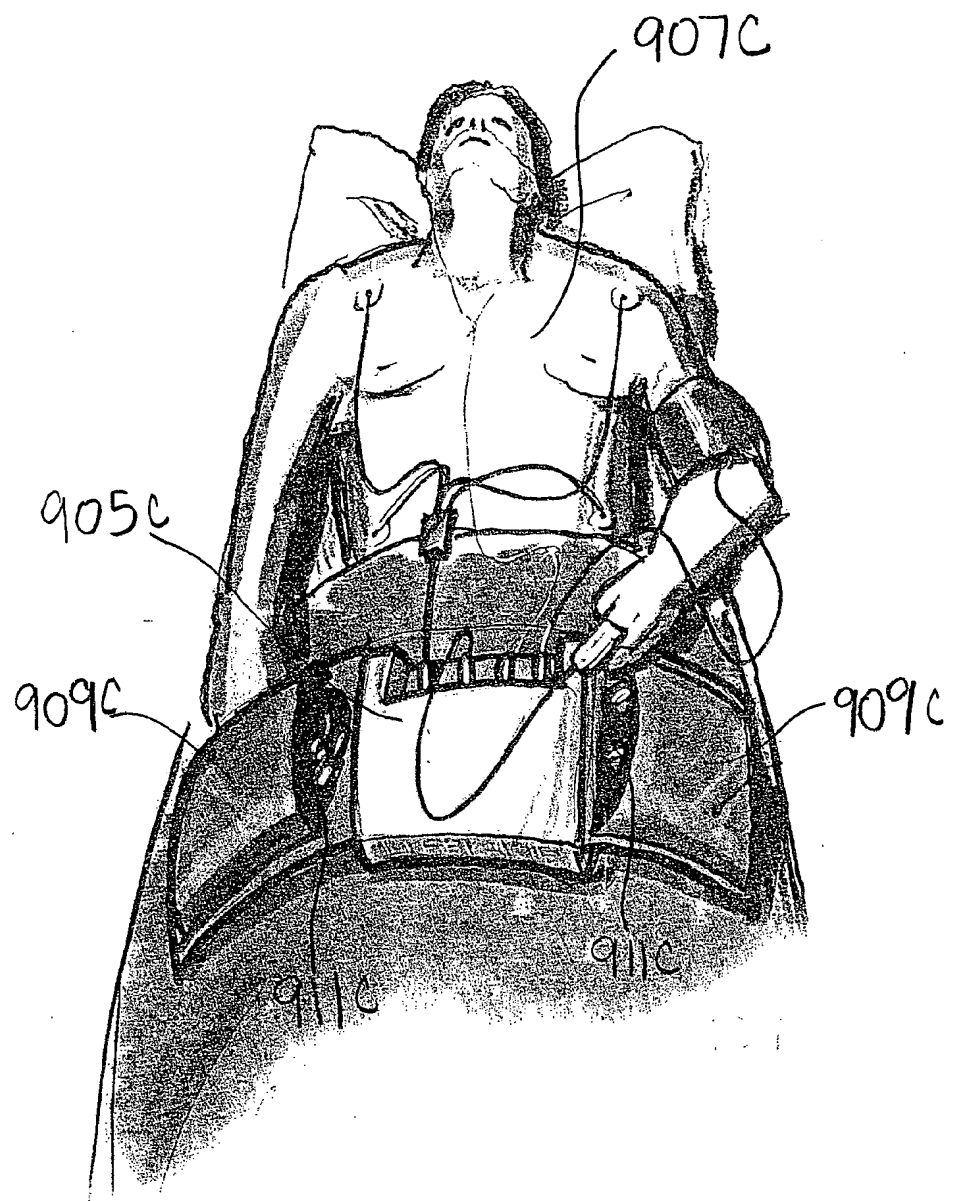


Figure 10C

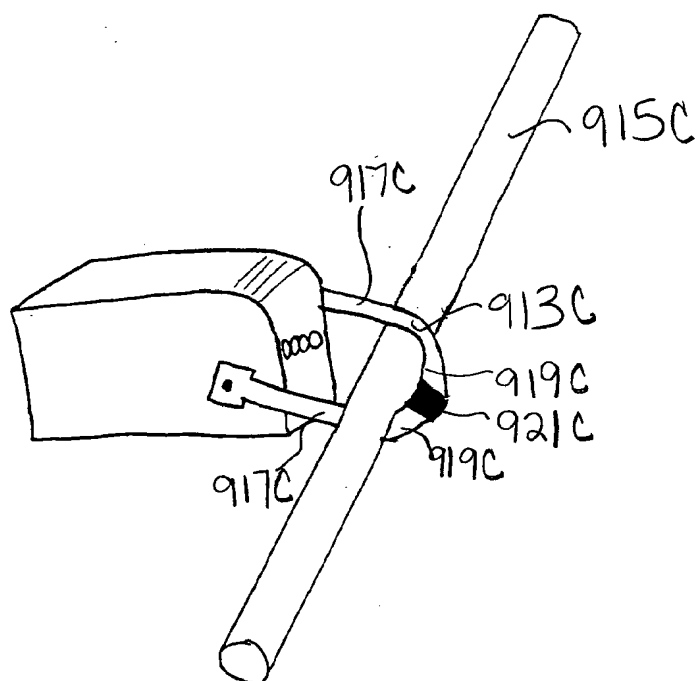


Figure 11C

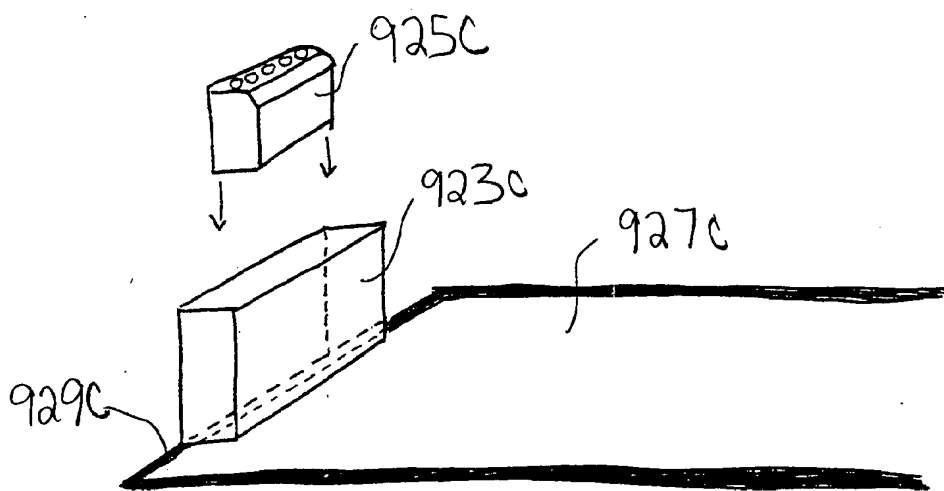


Figure 12c

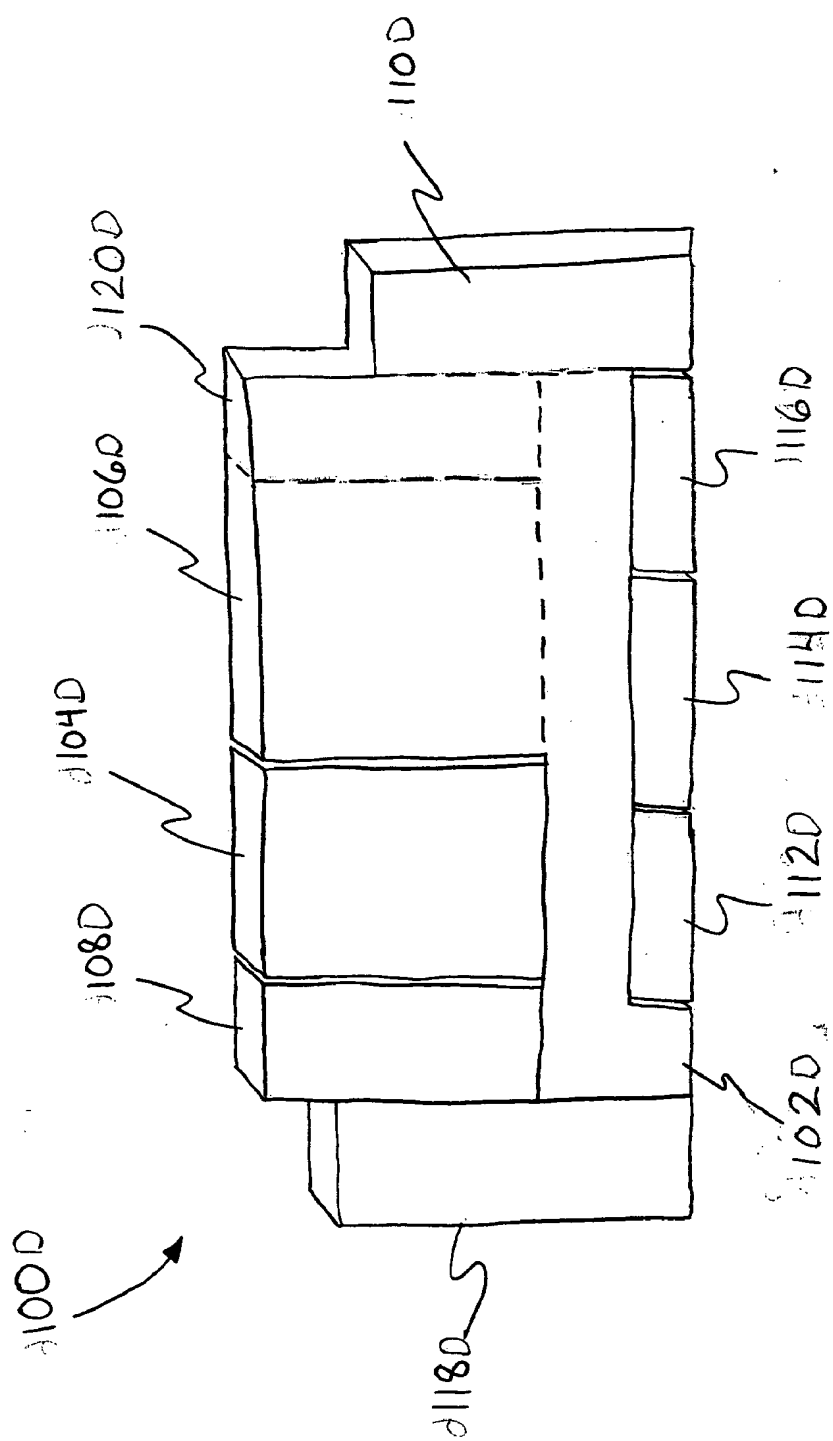


FIGURE 1D

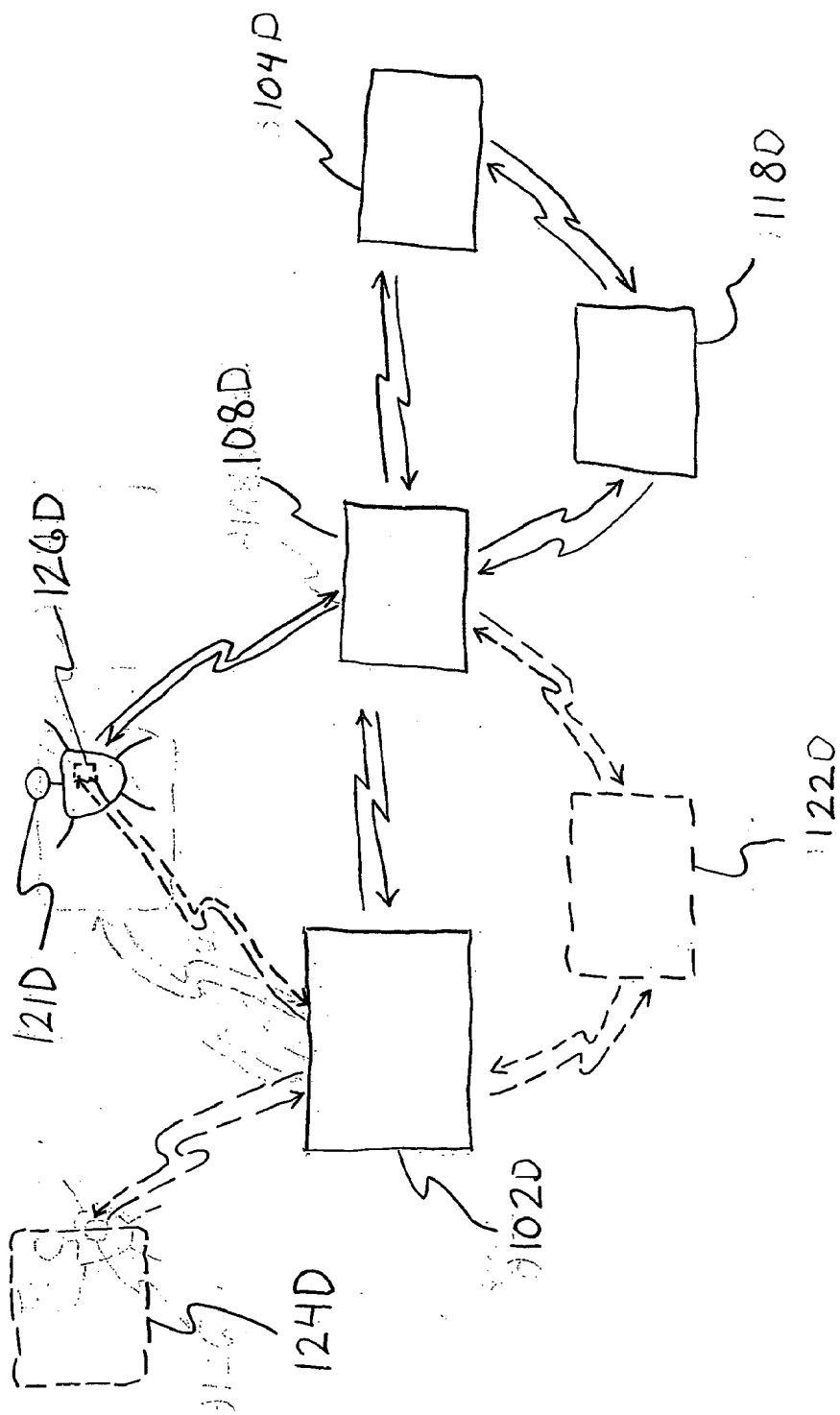


FIGURE 20

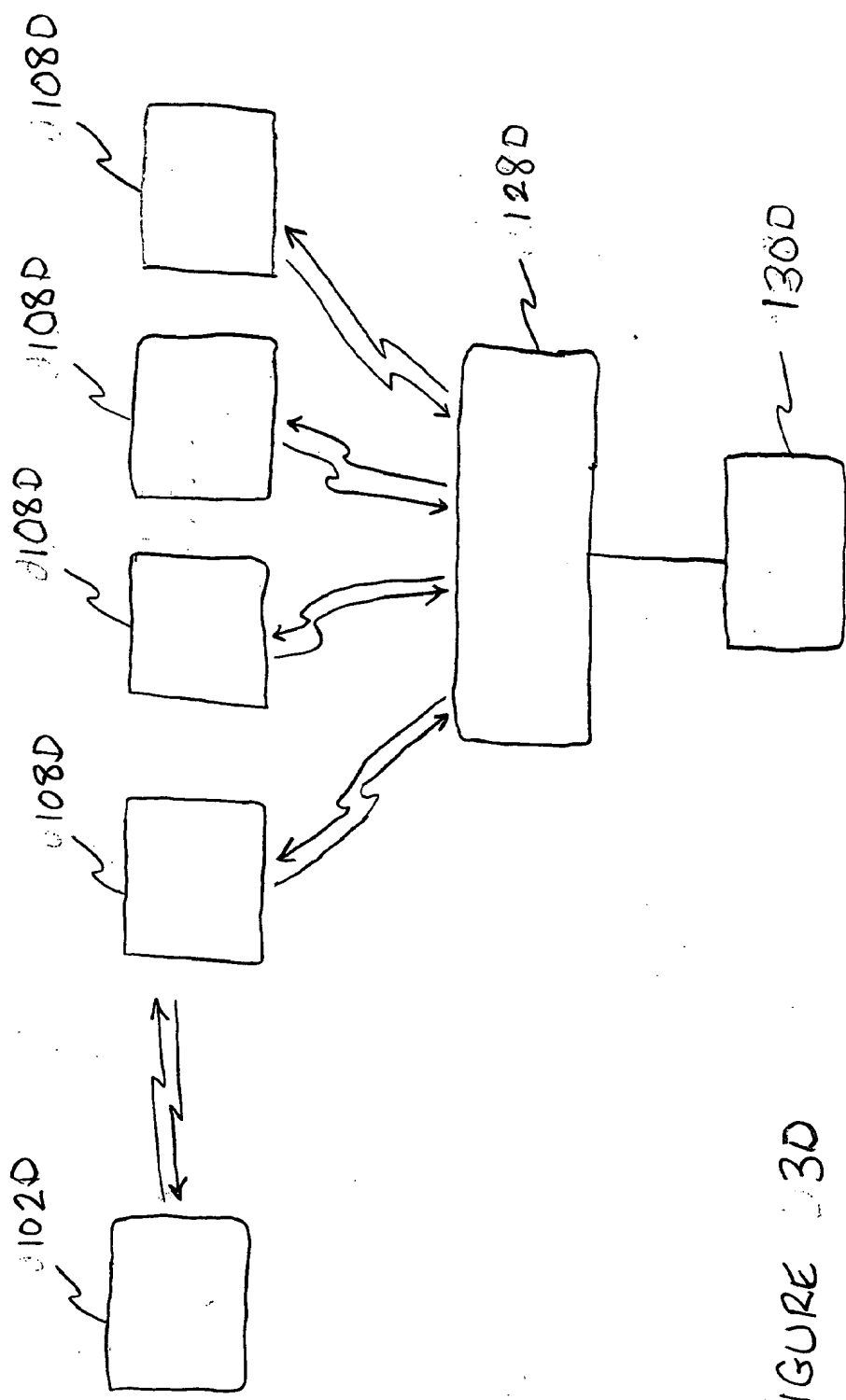
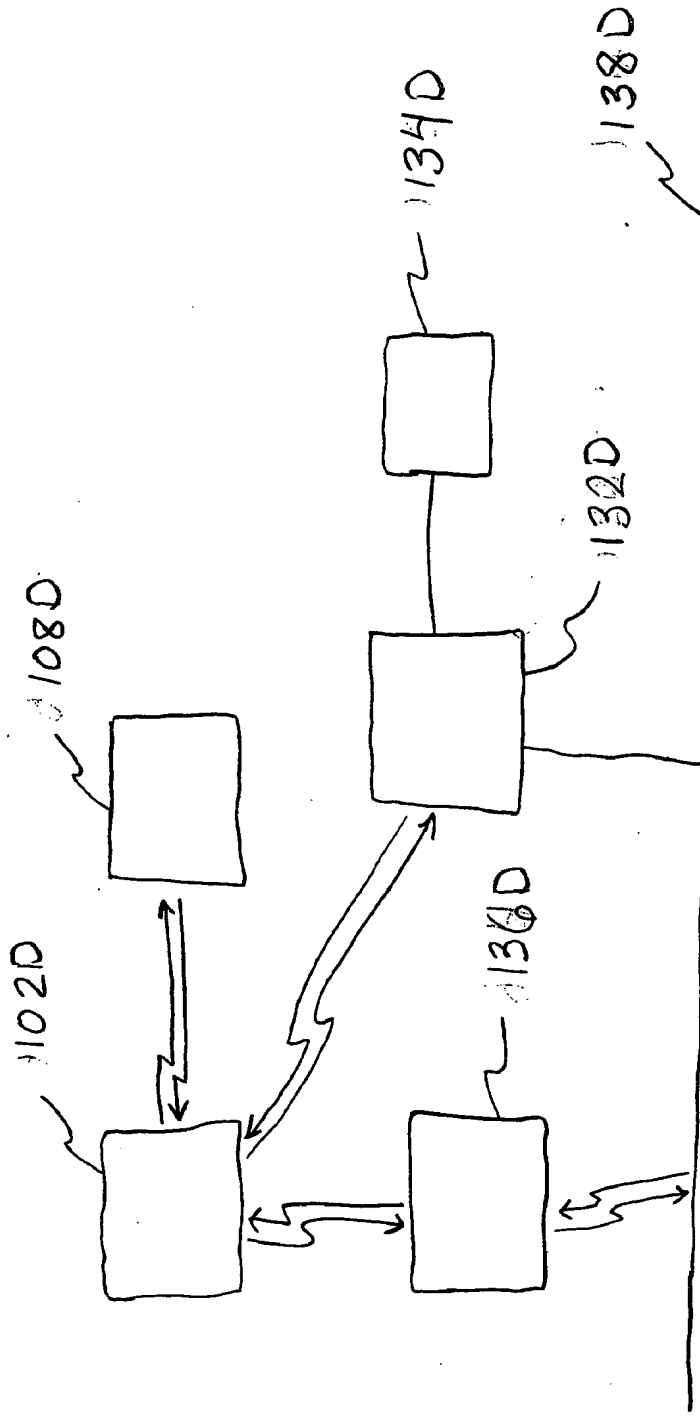


FIGURE 13D

FIGURE 4D



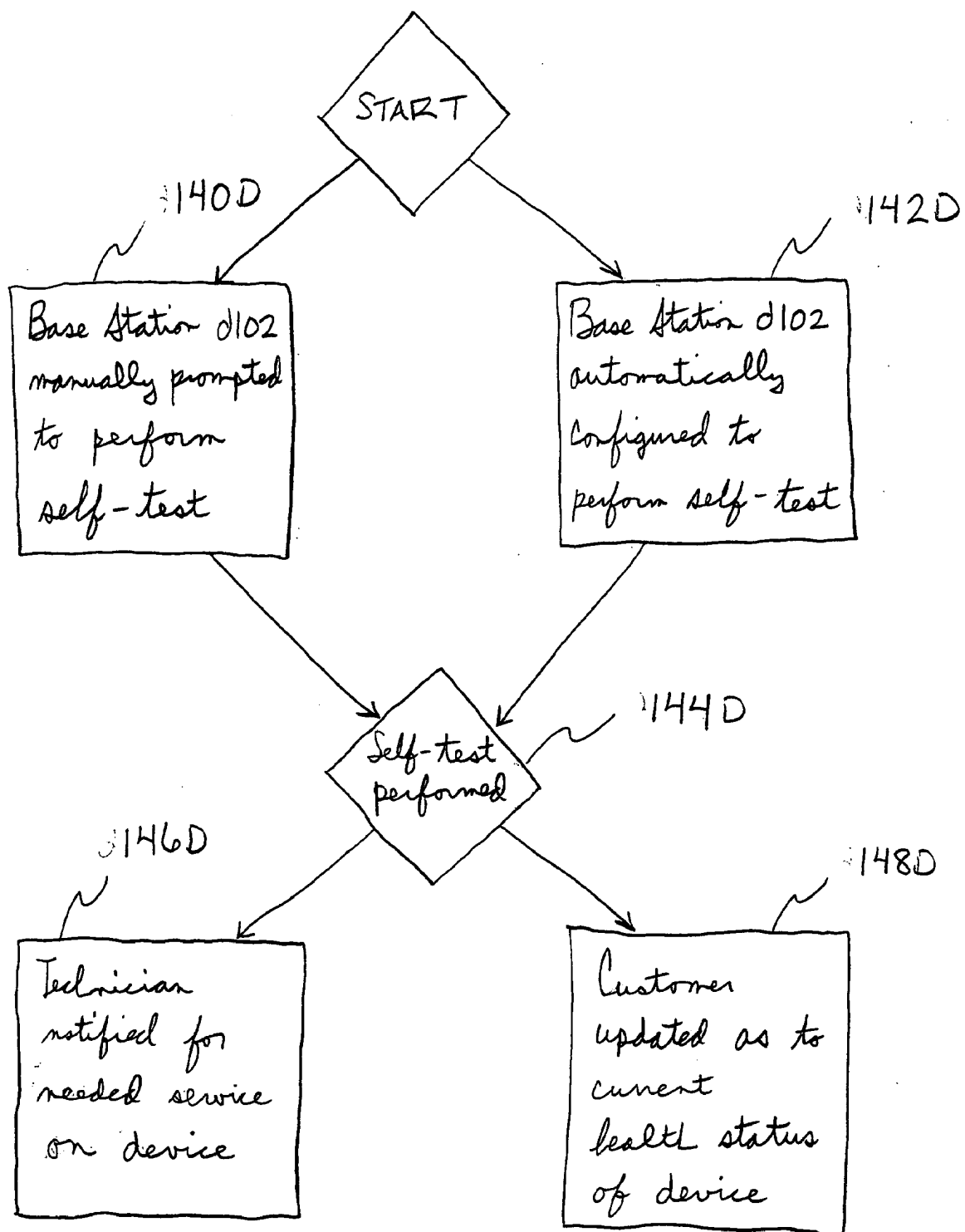


FIGURE D5D

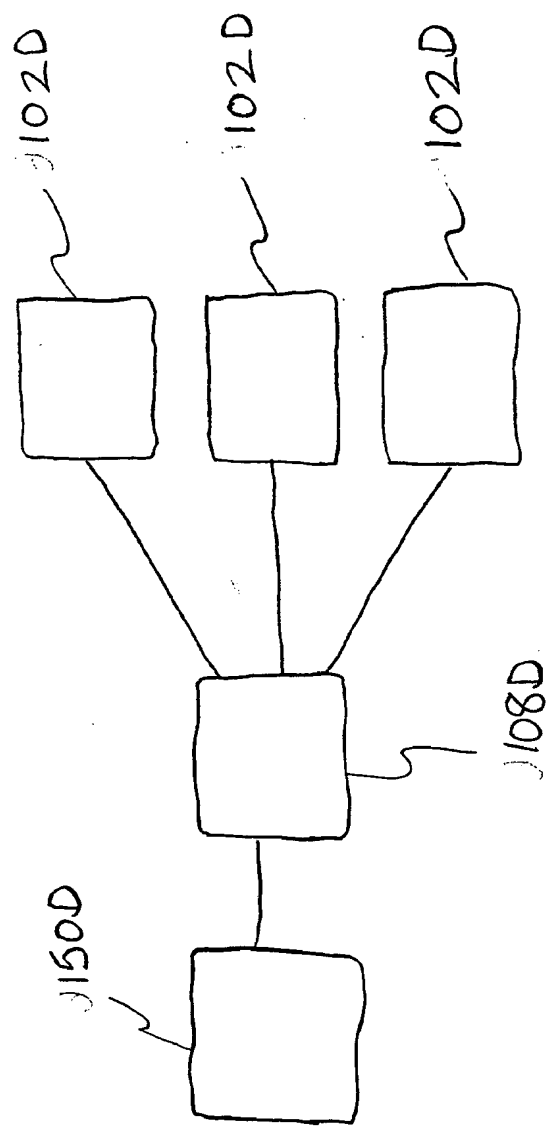


FIGURE 16D

Fig. 1E

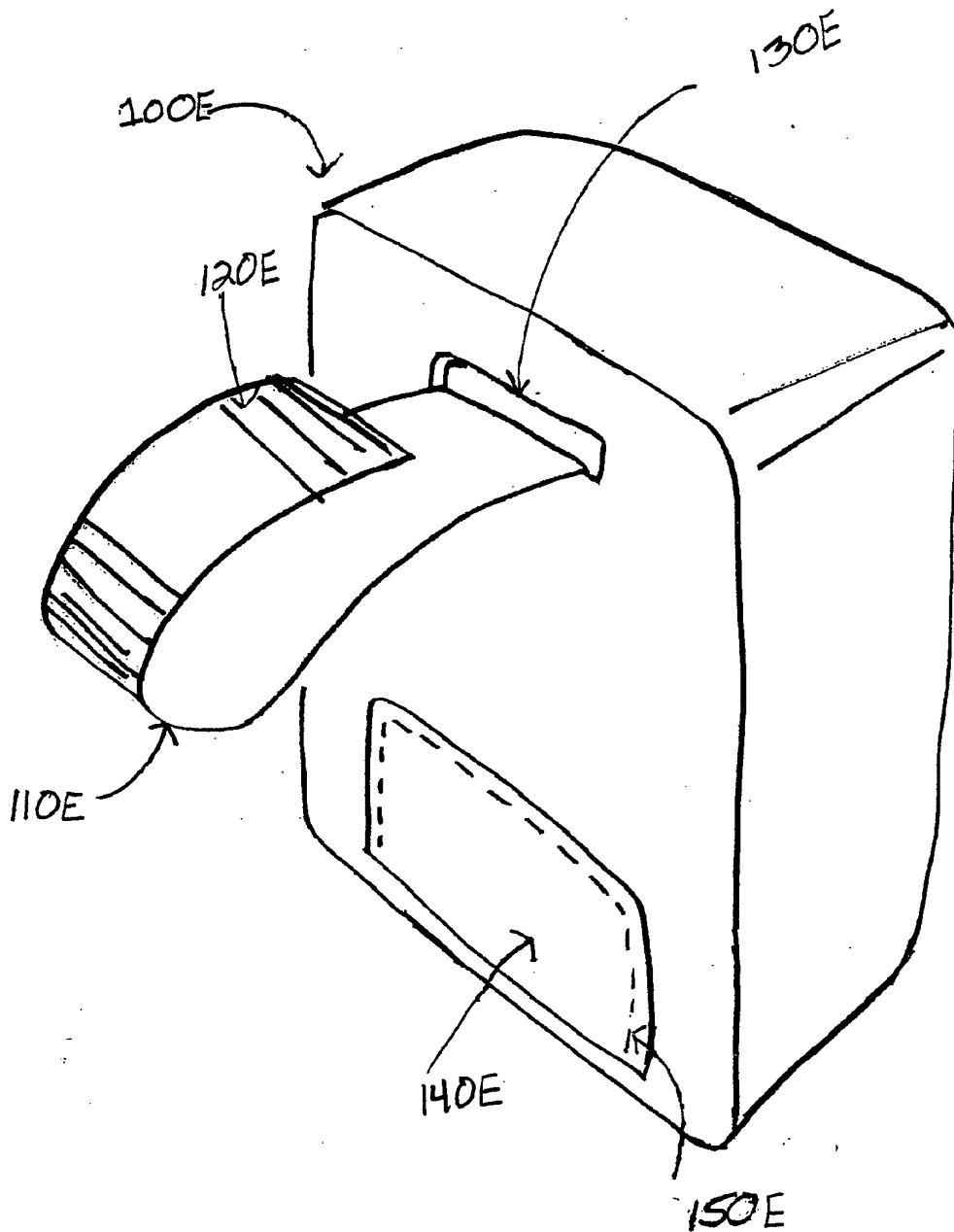
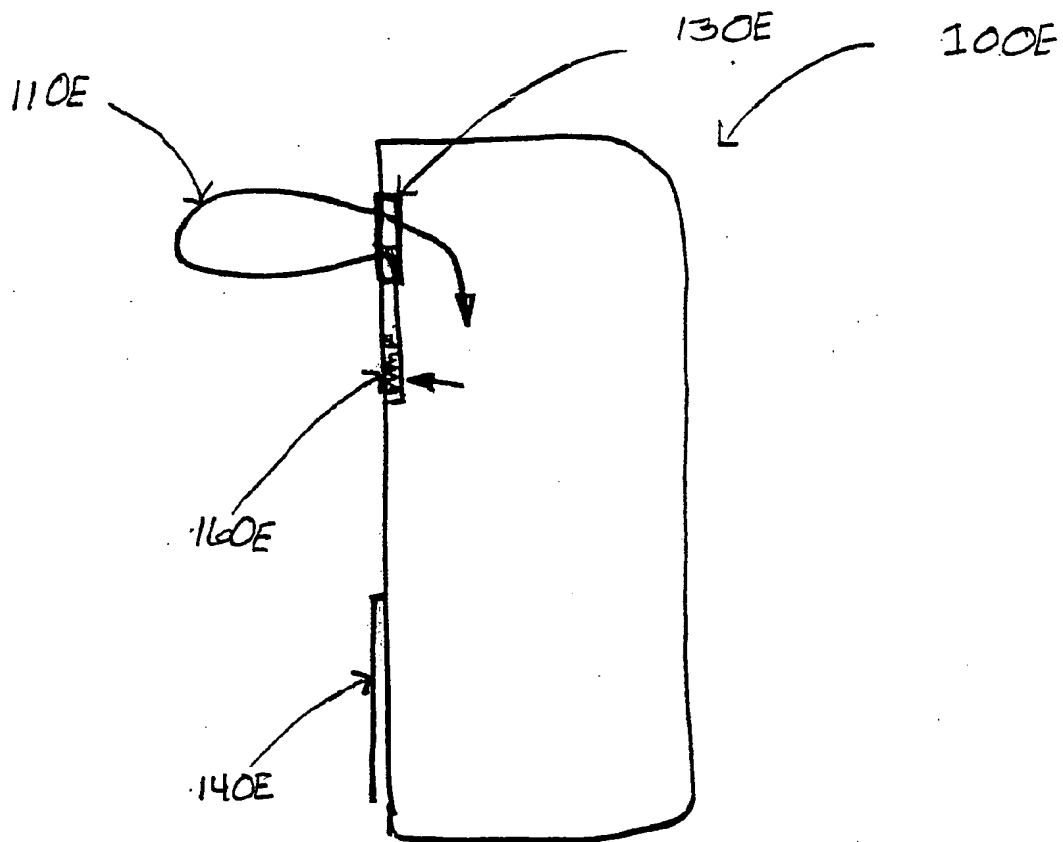


Fig. 2E



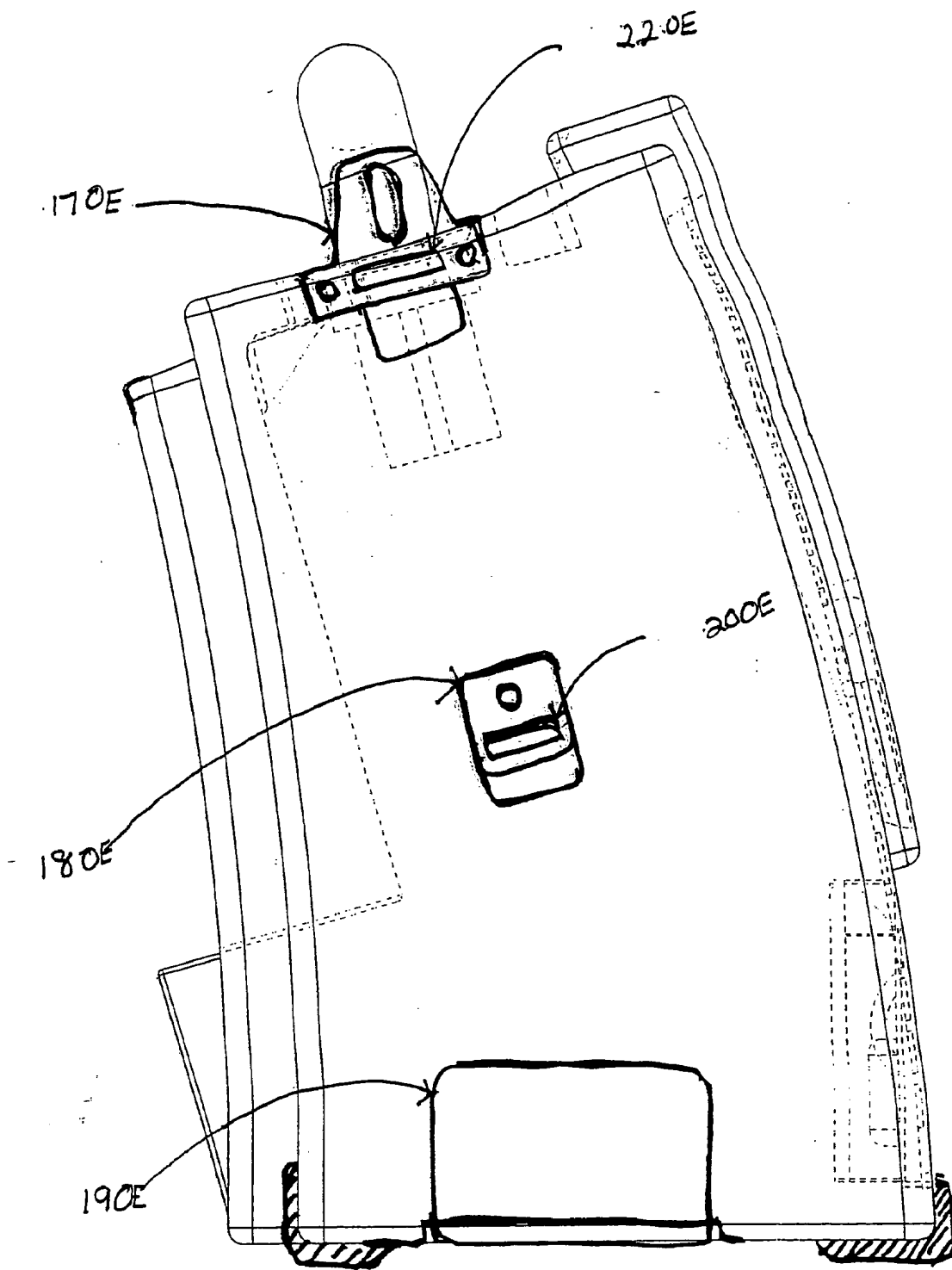


Fig. 3E

Fig. 4E

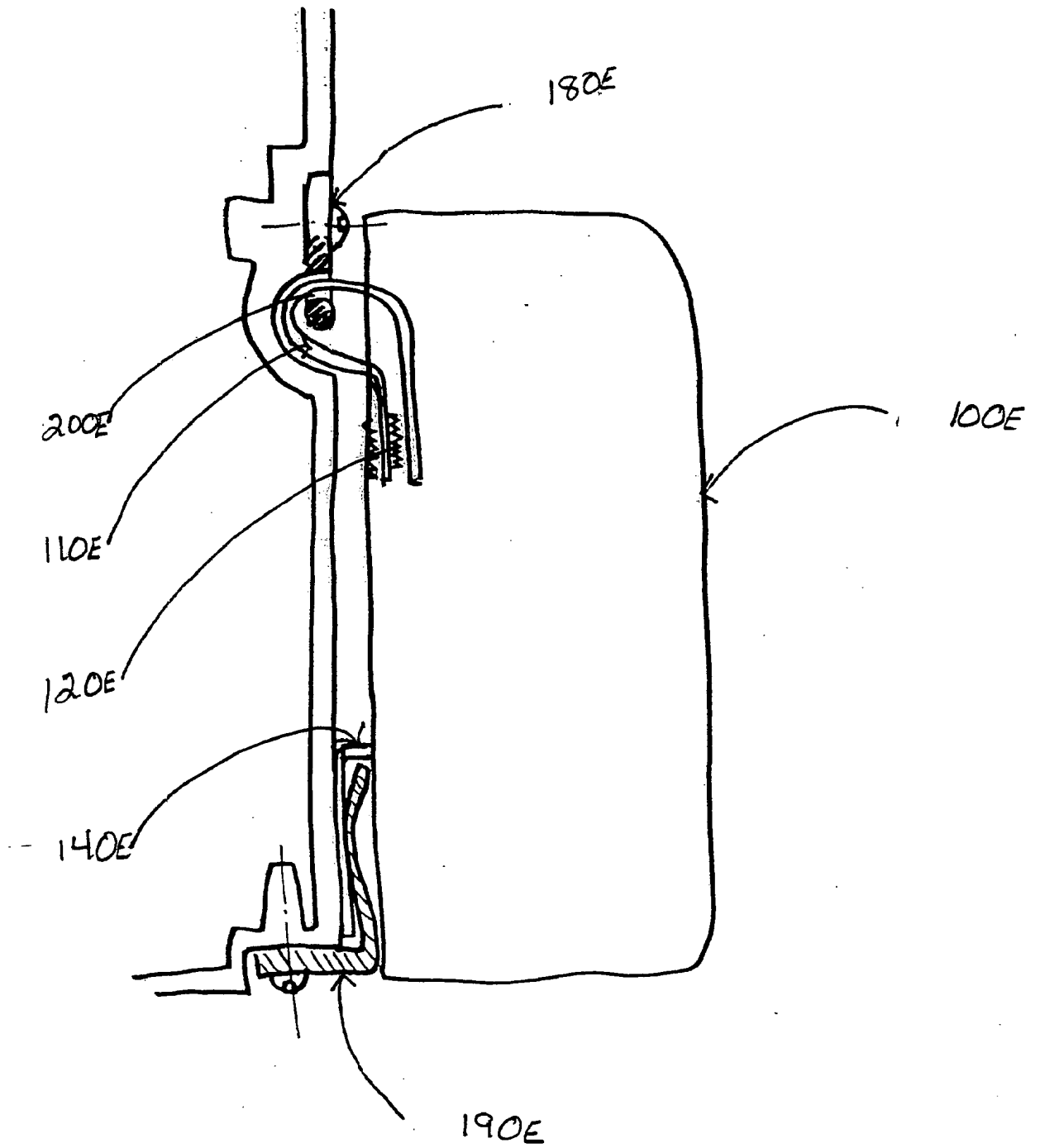


Fig. 5E

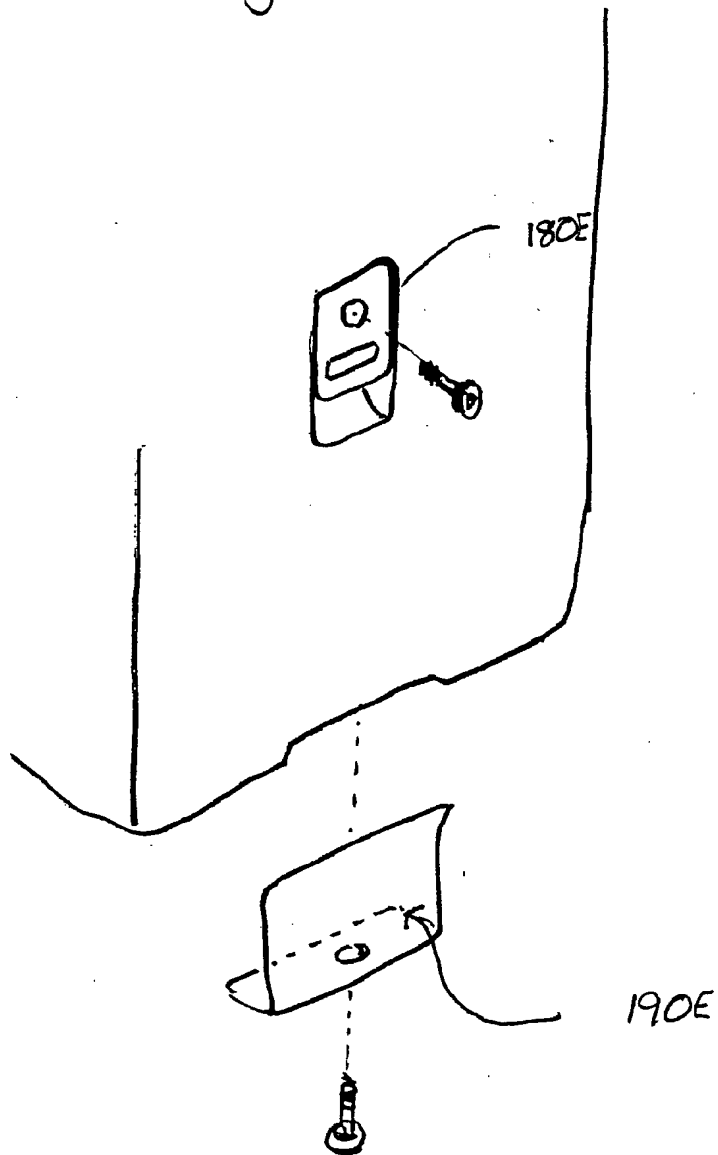


Fig. 6E

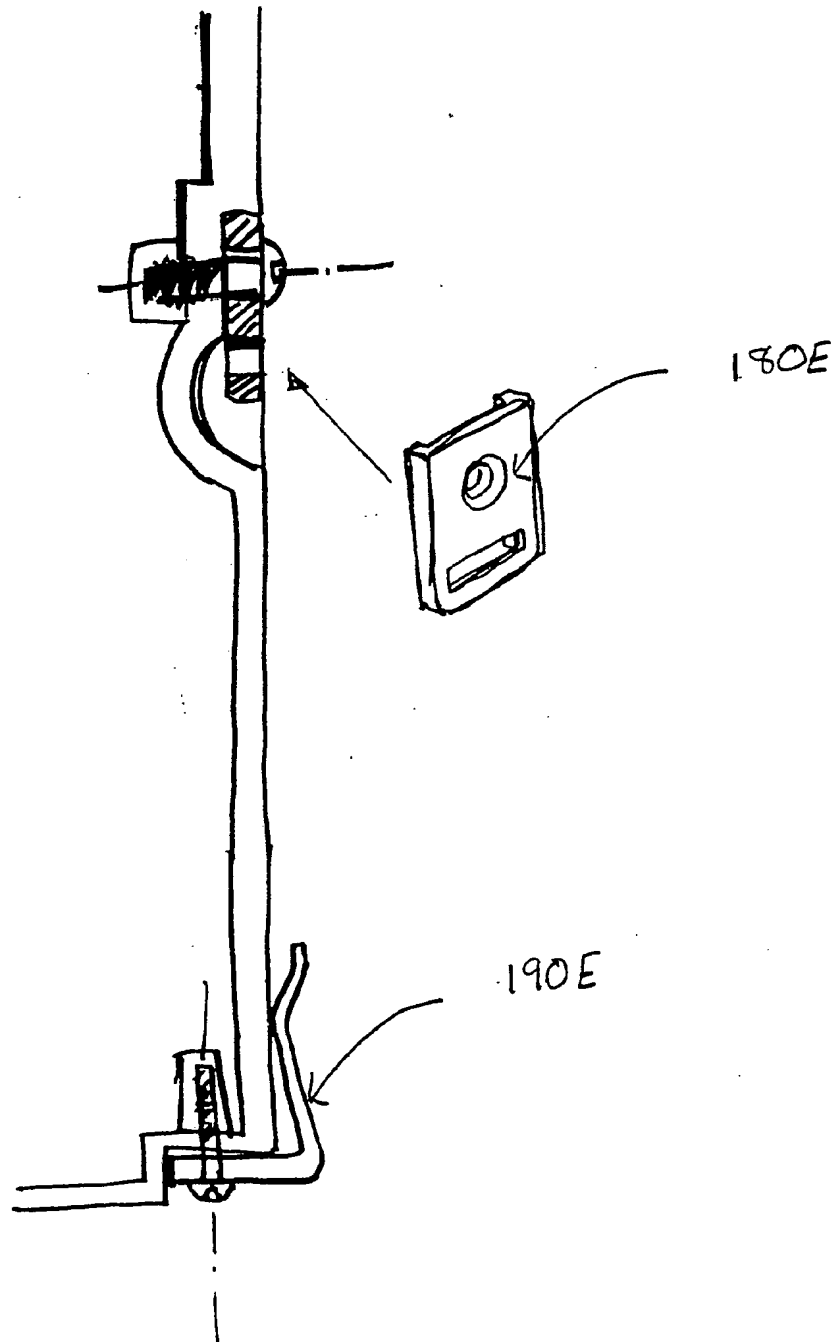


Fig. 7E

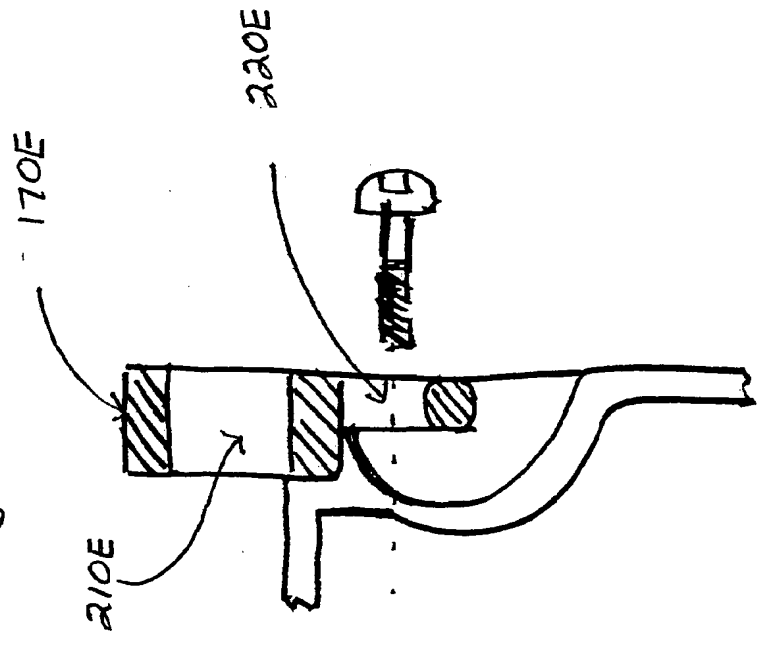


Fig. 8E

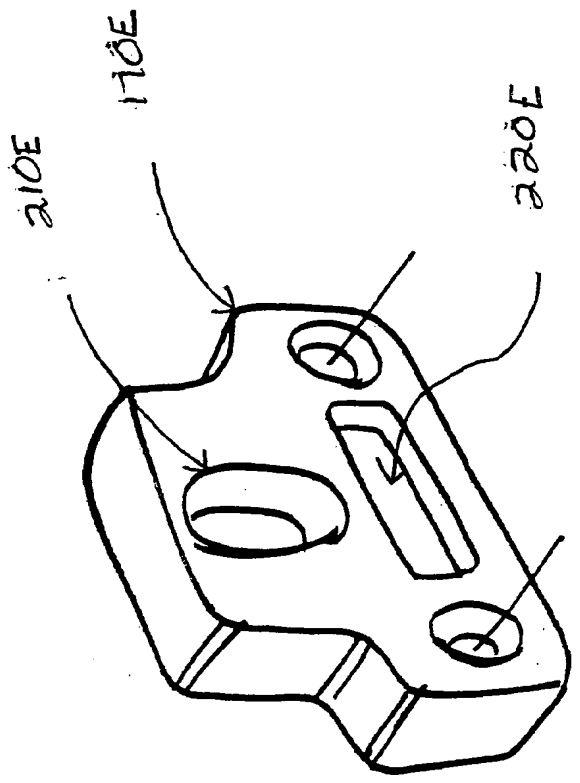


Fig. 9E

240E
230E

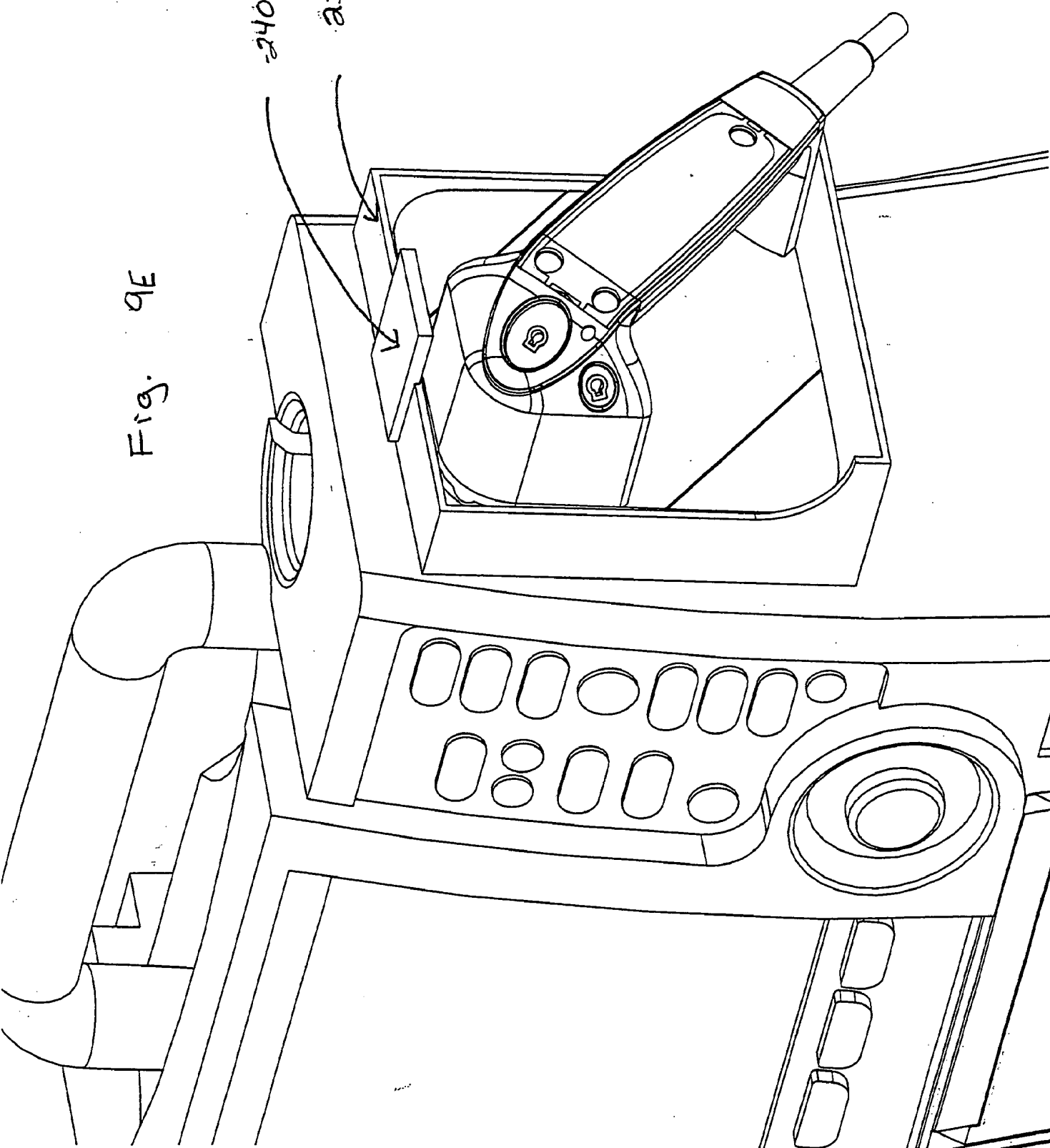


Fig. 10E

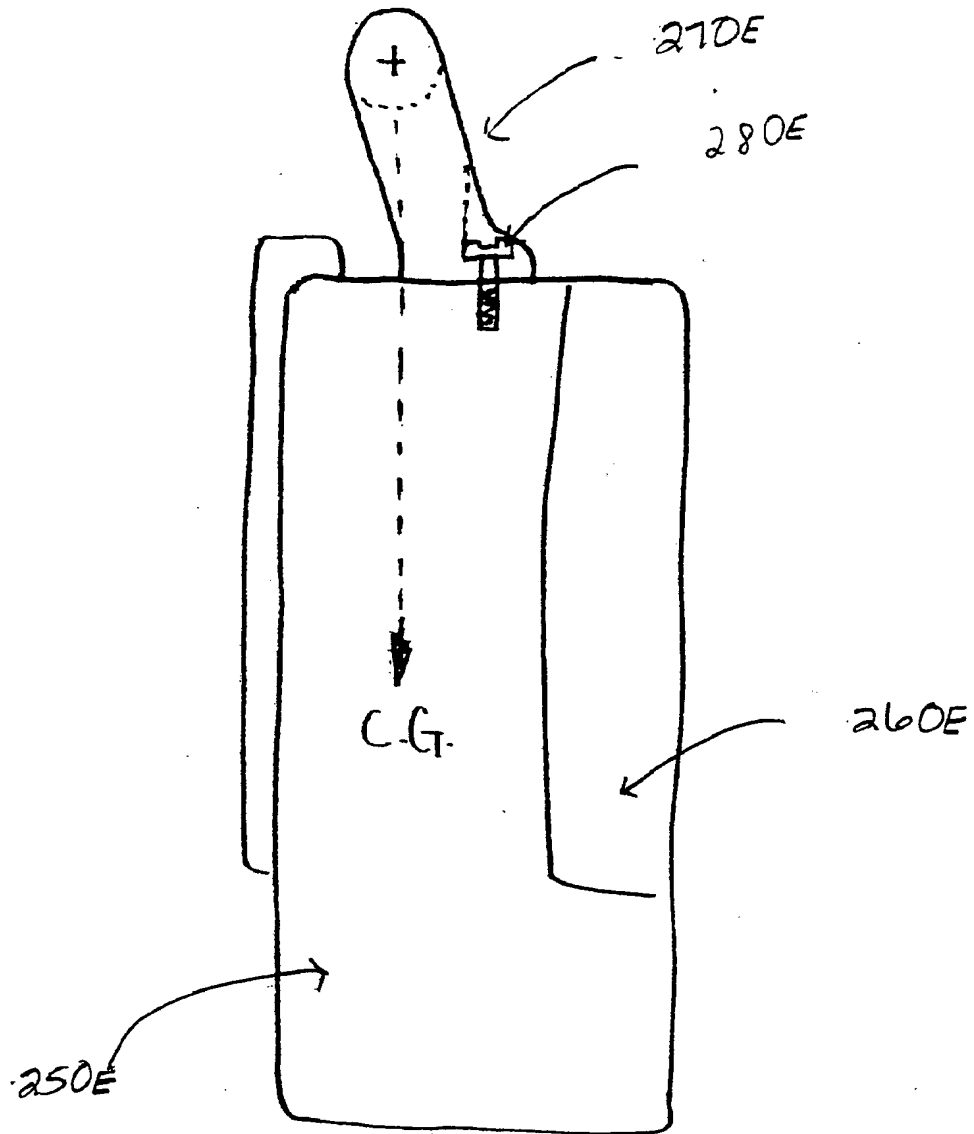


Fig. 11E

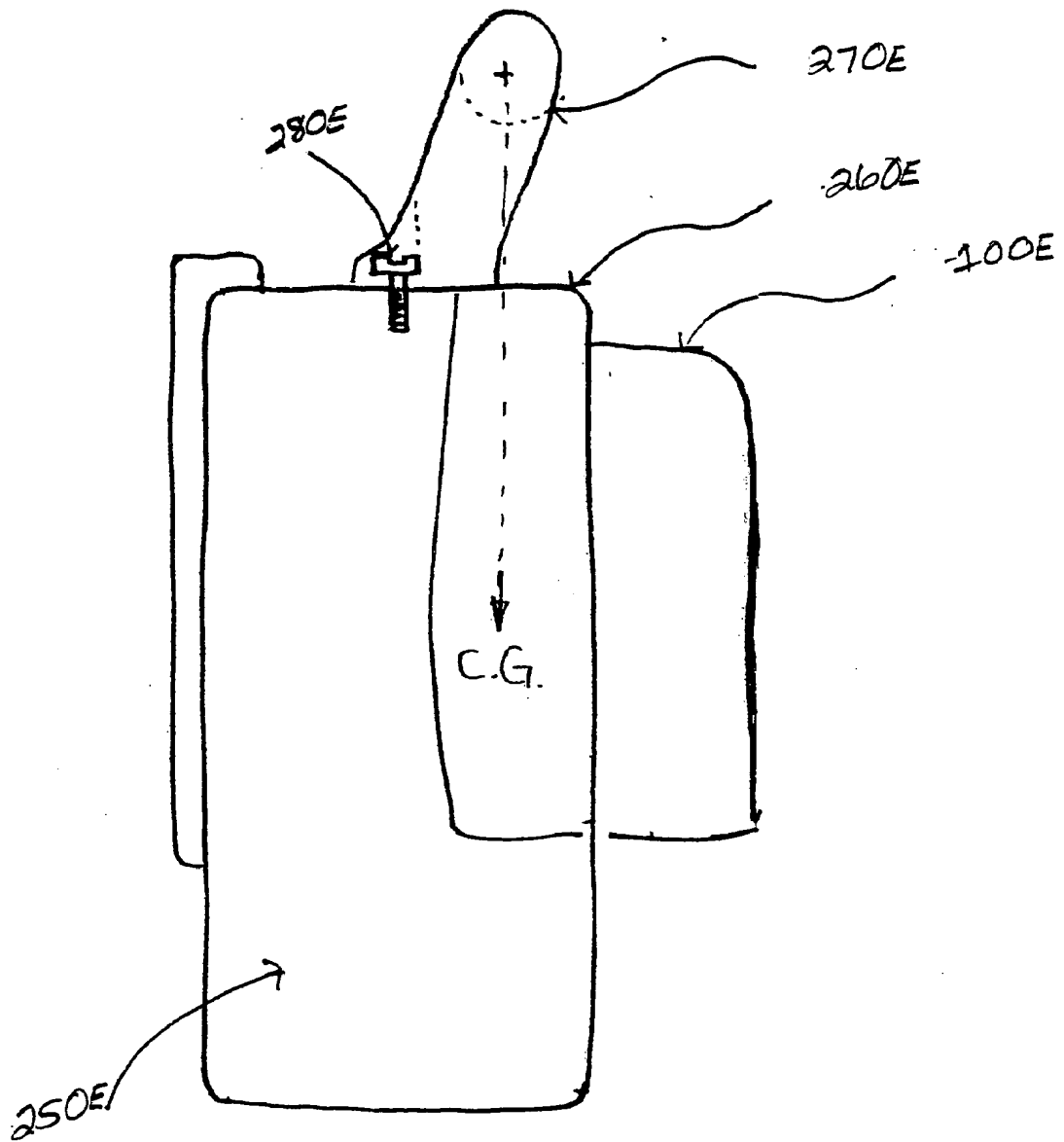


Fig. 12E

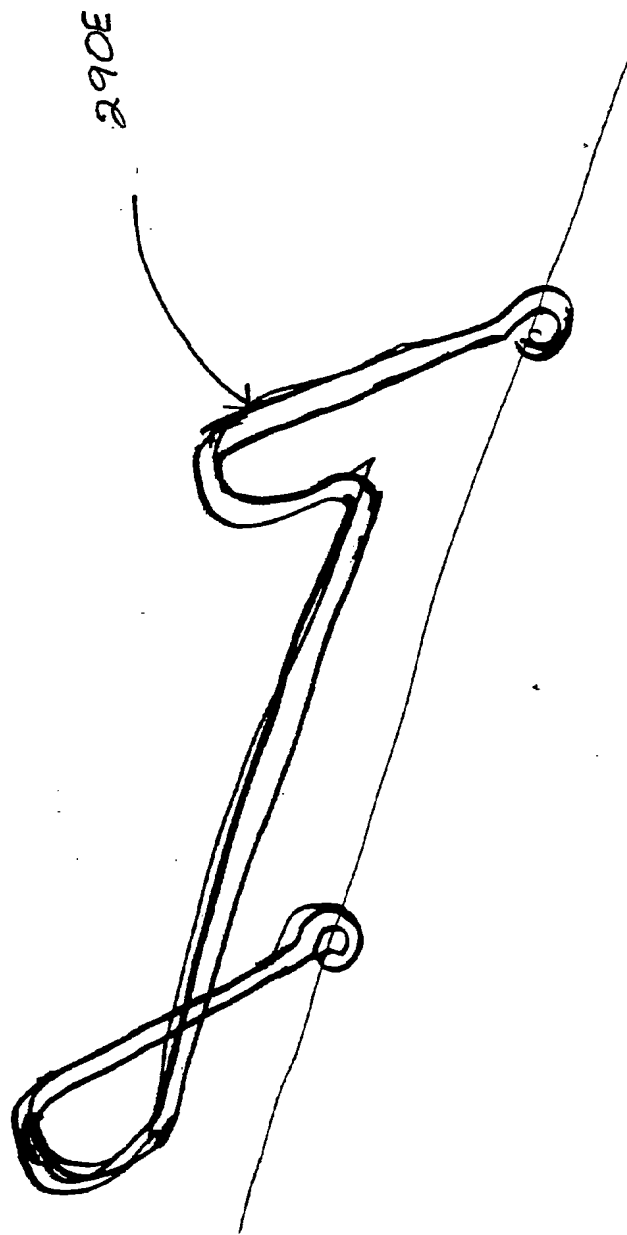


Fig. 13E

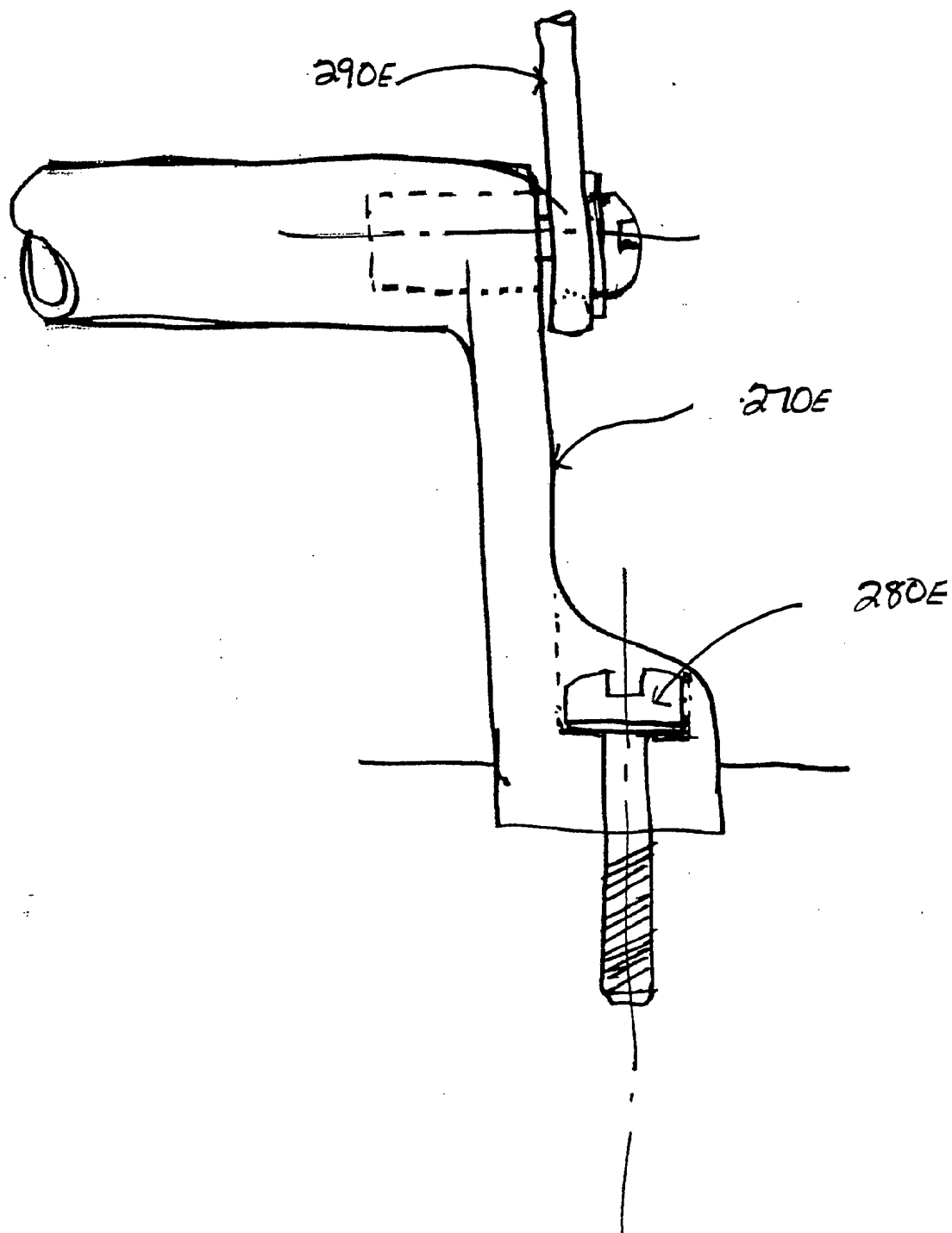


Fig. 14E

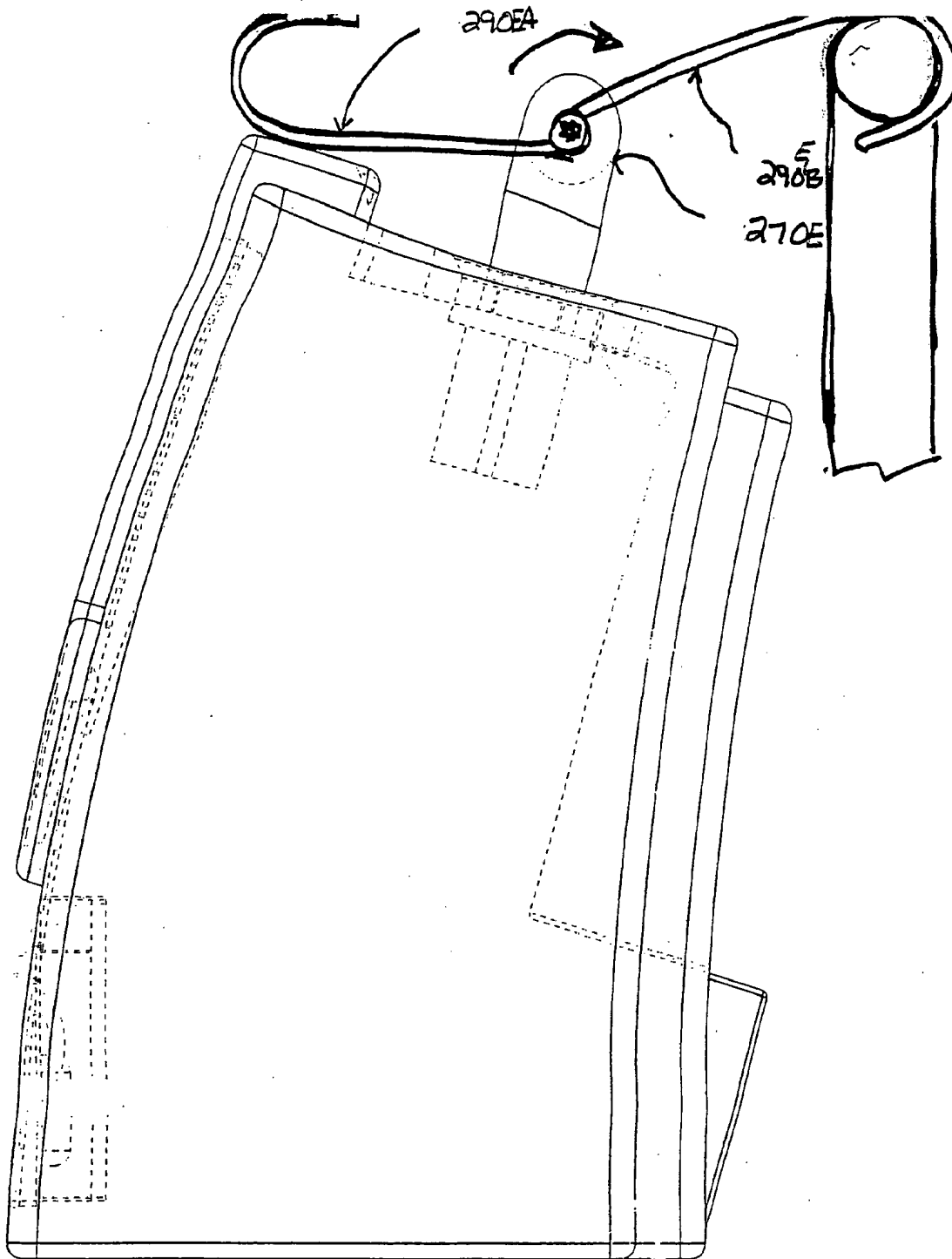


Fig. 15E

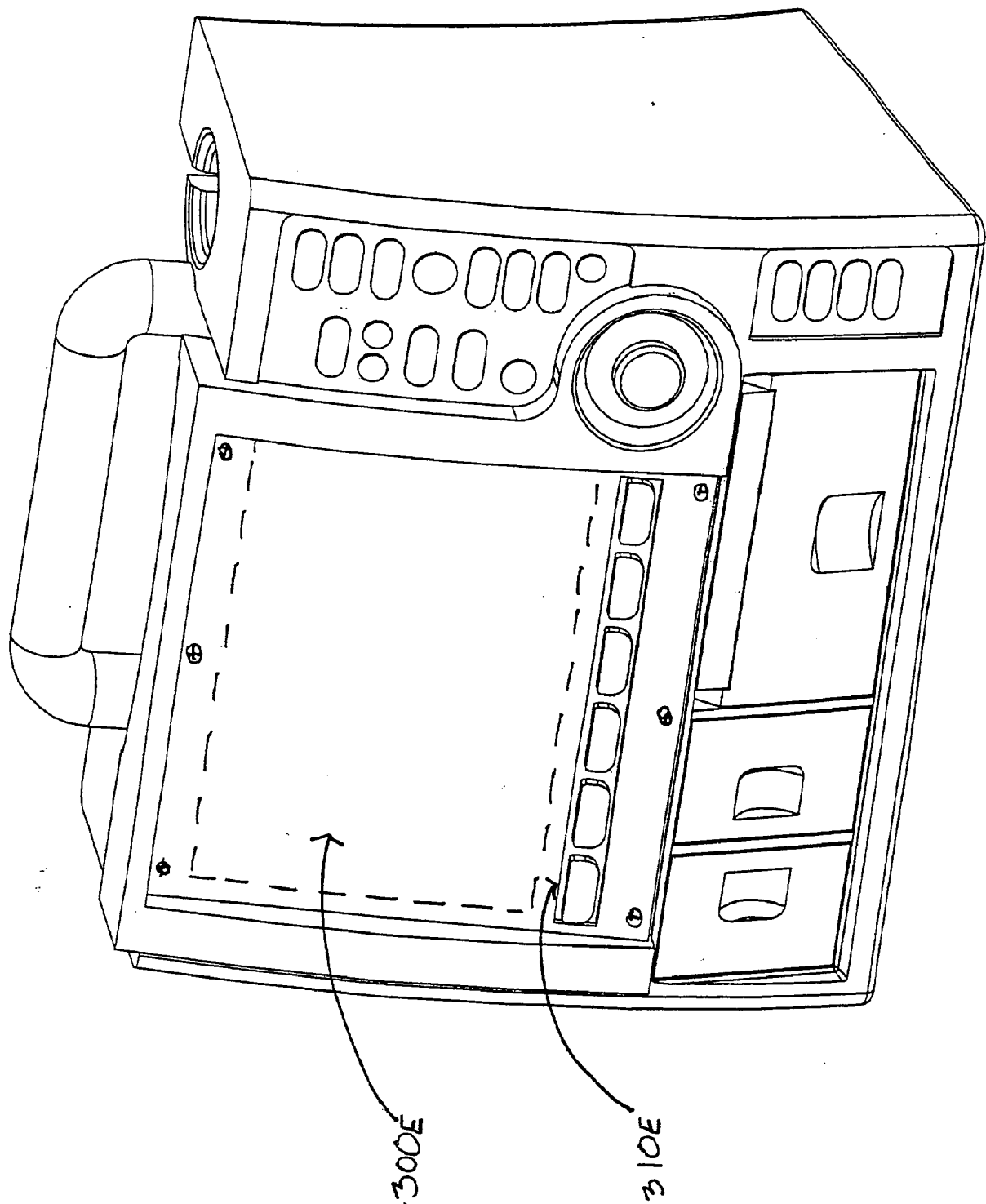


Fig. 16E

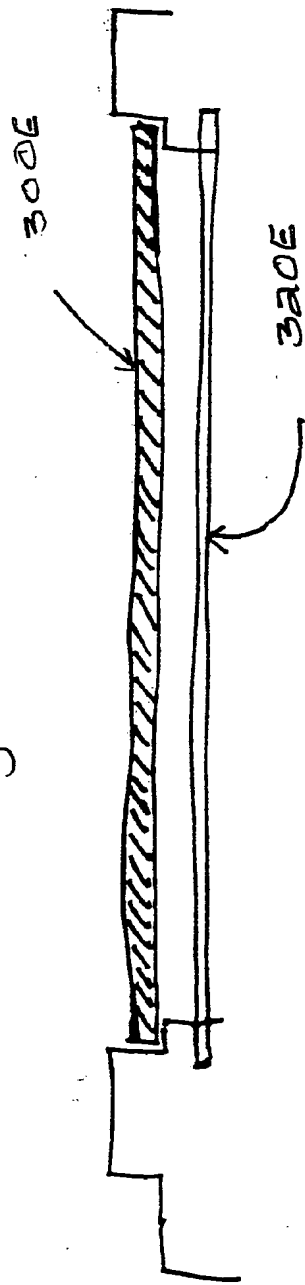


Fig. 17E

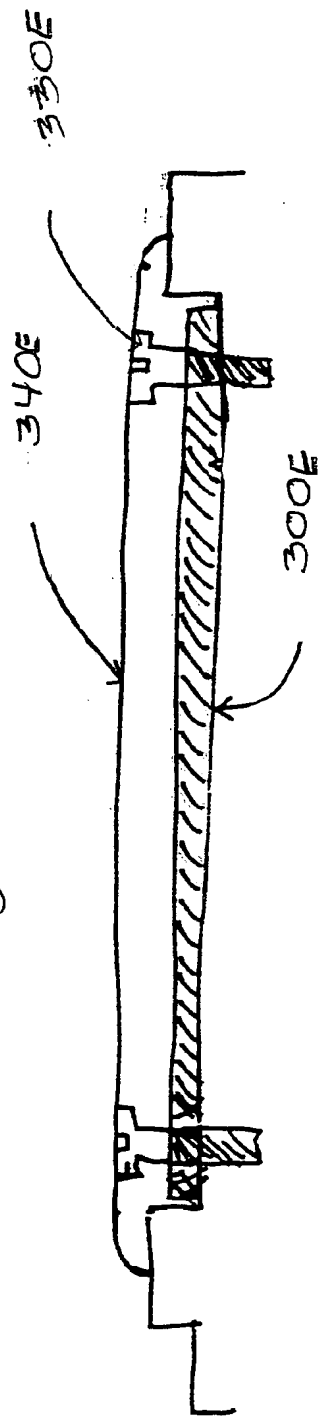
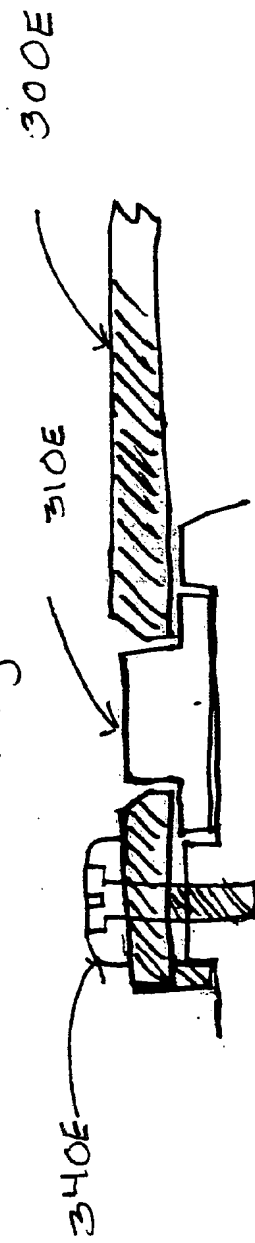


Fig. 18E



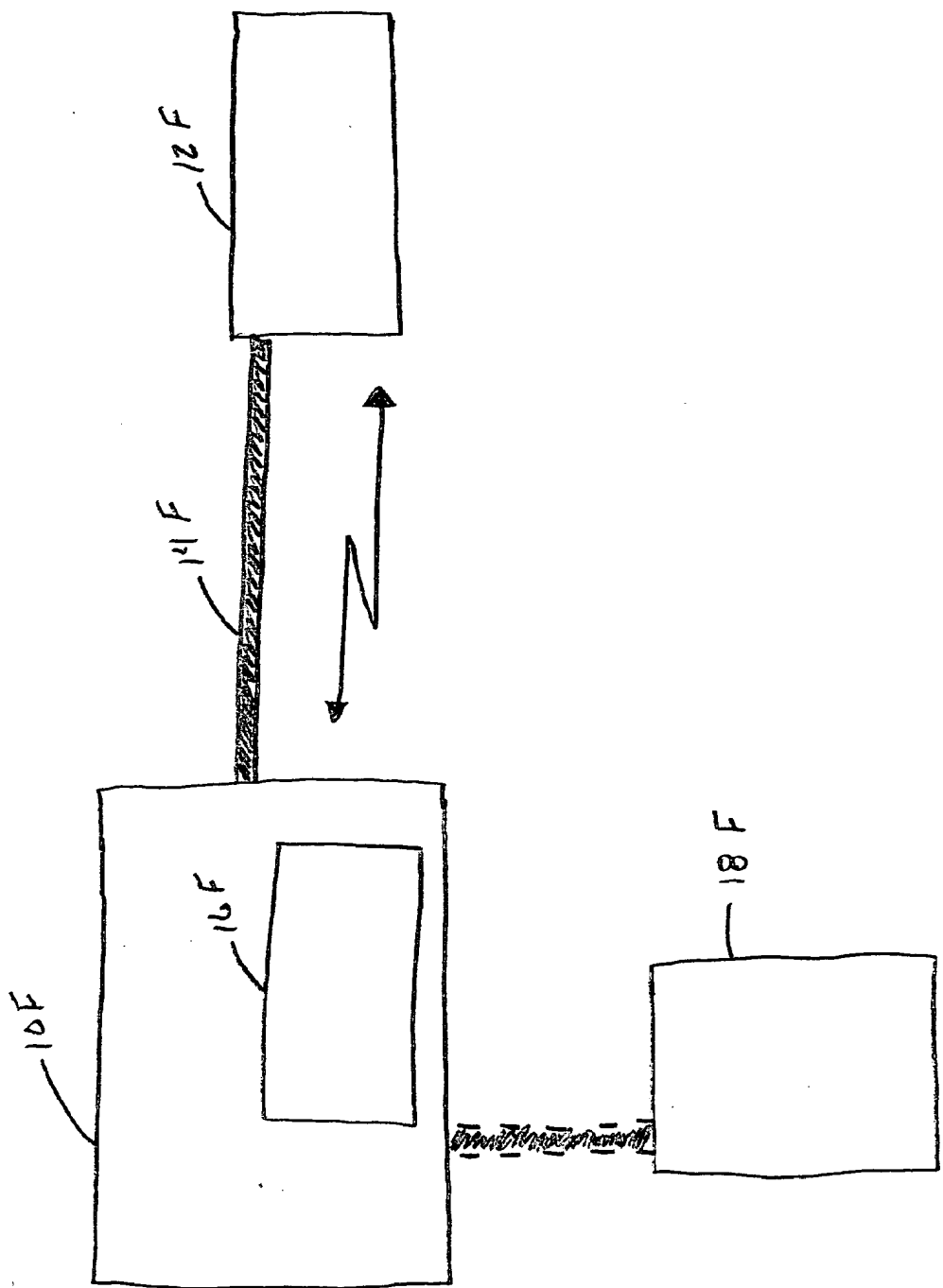


Figure 1F

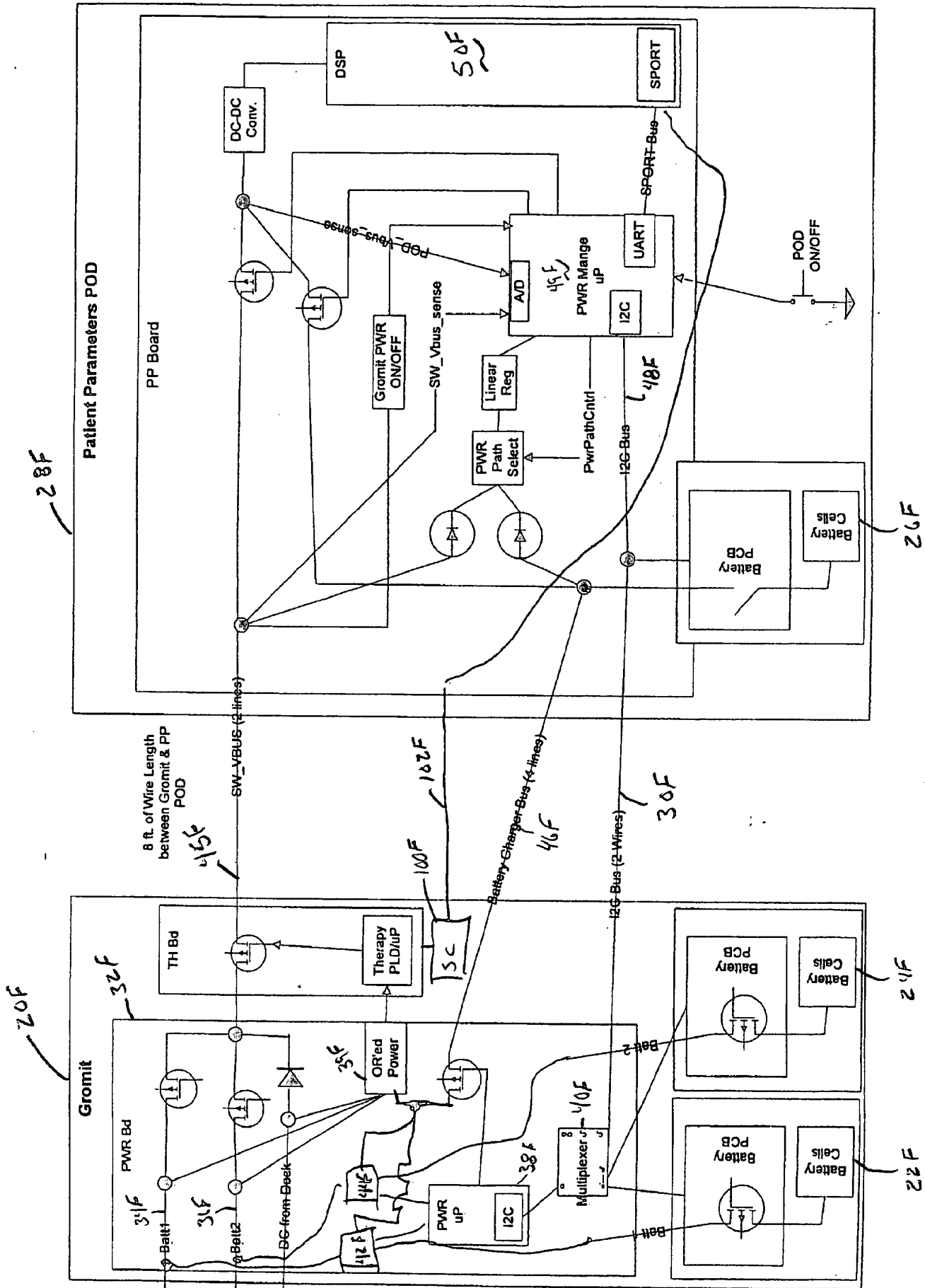


Figure 2F

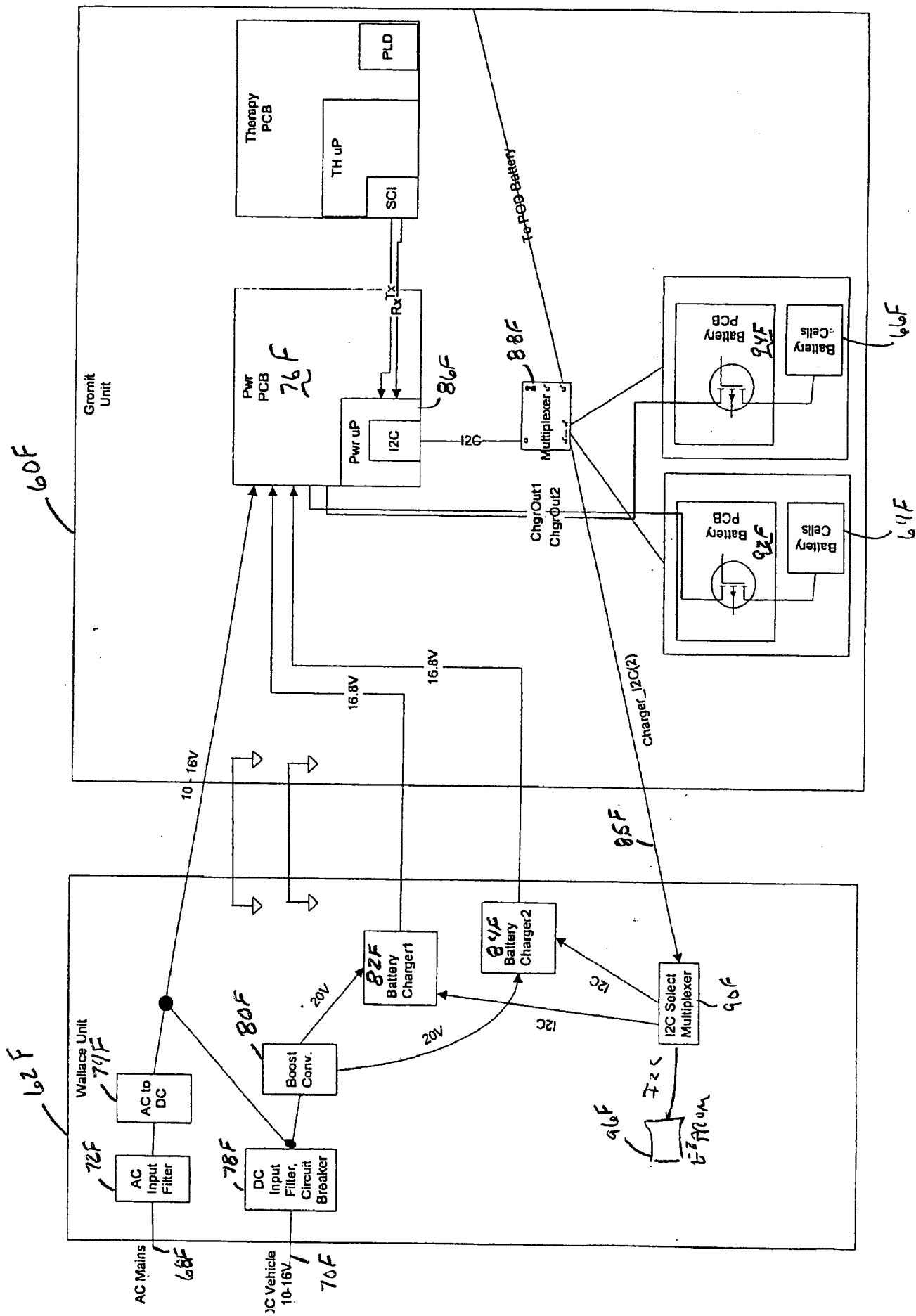


Figure 3F